FEDERAL TRADE COMMISSION

I N D E X (PUBLIC RECORD)

WITNESS:	DIRECT	CROSS	REDIRECT	RECROSS
Levy		2036(US)	2137	2177(SP)
				2182(US)
				2187(US)
Hoffman	2190	2284(SP)	2376	2380(US)
		2318(US)		

EXHIBITS	FOR ID	IN EVID
Commission		
Number 600		2231
Number 605		2243
Number 636		2237
Number 1653		2281
Number 1655		2260
Number 1656		2284
Schering		
Number 224		2073
Number 225		2071
Number 226		2072
Upsher		
Number 21		2068
Number 1025		2373

Upsher		
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OTHER EXHIBITS REFERENCED	PAGE
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Schering		
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Upsher		
USX 767		2329
USX 778		2359
USX 816		2336
USX 1036		2363

FEDERAL TRADE COMMISSION

In the Matter of:	)
SCHERING-PLOUGH CORPORATION,	)
a corporation,	)
and	)
UPSHER-SMITH LABORATORIES,	) File No. D09297
a corporation,	)
and	)
AMERICAN HOME PRODUCTS,	)
a corporation.	)
----------	)

Wednesday, February 6, 2002

9:30 a.m.

TRIAL VOLUME 10

PART 1

PUBLIC RECORD

BEFORE THE HONORABLE D. MICHAEL CHAPPELL

Administrative Law Judge

Federal Trade Commission

600 Pennsylvania Avenue, N.W.

Washington, D.C.

Reported by: Susanne Bergling, RMR

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P R O C E E D I N G S

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JUDGE CHAPPELL: Good morning, everyone.

ALL COUNSEL: Good morning, Your Honor.

JUDGE CHAPPELL: Let's reconvene docket 9297.

Mr. Levy, I remind you you are still under oath.

THE WITNESS: Yes, sir.

JUDGE CHAPPELL: Mr. Curran, you may proceed with your cross examination.

MR. CURRAN: Thank you, Your Honor.

Whereupon--

NELSON L. LEVY

a witness, called for examination, having previously been duly sworn, was examined and testified further as follows:

CROSS EXAMINATION

BY MR. CURRAN:

Q. Good morning, Dr. Levy.

A. Good morning, Mr. Curran.

Q. I'd like to begin this morning by picking up on a few of the matters we were discussing yesterday. Do you recall our discussion of Zonagen?

A. Yes.

Q. Sir, Zonagen today has nine or ten full-time

employees, correct?

A. You know, I'm not sure. They have had to cut back their staff considerably, and I thought it was more than that, but they certainly have reduced their staff since I was there, and I don't know the number.

MR. CURRAN: Your Honor, may I approach the witness to hand him a document to attempt to refresh his recollection?

JUDGE CHAPPELL: I believe you need to lay a foundation first, Mr. Curran.

BY MR. CURRAN:

Q. So, Dr. Levy, how many full-time employees does Zonagen have today?

A. I said I don't know, sir.

Q. Do you know how many employees they ever had at a given point in time?

A. I -- you know, when I was on the board, you know, I think even then -- I don't recall the exact number, but let me see if I can sort of reconstruct it in my own mind for you, because I, you know, I'm trying to recall it.

Q. Well, permit me to try to cut to the chase here.

A. Sure.

Q. You don't recall sitting here today how many

full-time employees Zonagen has, correct?

A. At the present time, that's correct.

Q. Would it be helpful to you if I were to show you some published reports as to how many employees, full-time employees, Zonagen has today?

A. Certainly.

MR. CURRAN: Your Honor, may I approach?

JUDGE CHAPPELL: Now you may.

MR. CURRAN: Thank you, Your Honor.

BY MR. CURRAN:

Q. Dr. Levy, I'd like to refer your attention to the second page -- first of all, do you see this is an issue of Business Week Online?

A. Yes, I do.

Q. I'd like to refer your attention to the second page where there's a statement that says, "As a result of this decision, Zonagen reduced its personnel to the minimum required to maintain existing technologies and commitments and laid off more than one-half of the Company's employees. Currently, the Company has 9 full-time employees."

A. Okay.

Q. Do you see that, sir?

A. Yes, sir.

Q. Sir, do you have any reason to doubt the

accuracy of this document?

A. No.

MR. CURRAN: Your Honor, may I approach the witness again for the same purpose?

JUDGE CHAPPELL: Yes.

BY MR. CURRAN:

Q. Dr. Levy, do you see this is an article from the Wall Street Journal?

A. Yes, sir.

Q. It's a transcript of an interview with Joseph Podolski.

A. Yes.

Q. Does that name mean anything to you?

A. Yes.

Q. Who is he?

A. Joe is the CEO. He had previously been the VP of R&D, and when David Williams left to go to Texas Biotech, Joe was elevated to the CEO position.

Q. Sir, I'd like to refer your attention to the fifth page of this document. It is, oddly perhaps, called page 8 at the top.

A. Page 8?

Q. Yes.

A. Okay. Okay.

Q. And I'd like to refer your attention to the

part of the interview toward the bottom of the page.

A. Yes.

Q. Do you see the first quote from Mr. Podolski?

A. Yes, sir.

Q. Okay. "Actually, we've taken steps in the last year and a half to reduce our head count to the point where we have 10 employees."

A. Yes.

Q. Sir, Zonagen today has nine or ten full-time employees, correct?

A. According to this. As I said, I don't know. I'm just relying on these documents, but they -- I think this -- I have no reason to, you know, to doubt these documents.

Q. Sir, do you recall yesterday discussing Viagra's recent sales?

A. Yes, sir.

Q. And you testified, I believe, that you thought that Viagra's sales were less than a billion dollars a year?

A. I believe so, yes.

Q. Would it be helpful to you to see some of the recent reports published by Pfizer as to the sales of Viagra?

A. Certainly.

MR. CURRAN: Your Honor, may I approach the witness?

JUDGE CHAPPELL: Yes.

BY MR. CURRAN:

Q. Sir, do you see this is an article from The Hartford Courant from about ten days ago?

A. Yes.

Q. Okay. I'd like to refer your attention, please, to the second page of this document, and in particular, do you see the section on Pfizer?

A. Yes.

Q. Sir, do you see in that discussion that there's a reference to the anti-impotency drug Viagra, whose sales grew 13 percent to $1.5 billion?

A. Yes.

MR. CURRAN: Your Honor, may I approach the witness for the same purpose?

JUDGE CHAPPELL: You may.

BY MR. CURRAN:

Q. Dr. Levy, do you now have before you an issue of the Bloomberg News from February 4, 2002?

A. Yes.

Q. And sir, that is Monday of this week, correct?

A. Yes.

Q. Sir, I'd like to refer your attention to the

third paragraph in this document.

A. I see it.

Q. Do you see the reference to Pfizer having $1.5 billion in sales last year?

A. Yes, I do.

Q. Sir, Viagra, in fact, had $1.5 billion in sales last year, correct?

A. Apparently so, yes.

Q. Sir, do you also recall discussing with me yesterday whether or not Viagra has a side effect of flushing?

A. Yes.

Q. Sir, what's your understanding of the extent of the side effect of flushing --

A. I'm sorry --

Q. -- of Viagra?

A. -- I'm not sure I understand your question, sir.

Q. What percentage of patients who take Viagra experience flushing?

A. I don't know that number, sir.

MR. CURRAN: Your Honor, may I approach the witness?

JUDGE CHAPPELL: Yes.

BY MR. CURRAN:

Q. Sir, I've handed you an article from a publication indicated as JAMA. Do you see that in the bottom left of that document?

A. Yes, I do.

Q. What does JAMA mean?

A. Journal of the American Medical Association.

Q. Is that a reputable journal in the medical field?

A. Yes.

Q. Sir, this article is entitled "Viagra Leads as Rivals Are Moving Up," correct?

A. Yes.

Q. Sir, I'd like to direct your attention to the middle column toward the bottom. Do you see the reference there to a Pfizer-funded 24-week fixed-dose study of 532 patients?

A. Yes.

Q. Sir, I want to read those two sentences.

"In the Pfizer-funded, 24-week, fixed-dose study of 532 patients, only 2% discontinued taking Viagra because of adverse events. The most frequent adverse events were headaches in 22% of the patients, flushing in 20% and dyspepsia in 10%."

Do you see that, sir?

A. Yes, I do.

Q. Okay. Sir, based on that study, Viagra has the adverse event of flushing in 20 percent of the patients, correct?

A. Yes.

Q. Now, sir, we also discussed at least briefly yesterday your experience at Abbott and Fujisawa, correct?

A. Yes.

Q. Okay. Sir, at Abbott, did you start the programs that led to several marketed drugs, including Hytrin, Biaxin and Ritonavir?

A. Yes.

Q. You started those programs?

A. Well, Biaxin was an in-licensed drug from Taisho, and so this is why I hesitated when I asked your question -- when I answered your question, because Abbott didn't discover Biaxin, but it was in-licensed under my supervision, and we began all the preclinical and subsequently the clinical development of that drug.

Q. That being Biaxin?

A. That's Biaxin, yes.

Q. Sir, when did you leave Abbott?

A. I left Abbott in 1984.

Q. Sir, Biaxin was approved by the U.S. Food and Drug Administration in 1991, correct?

A. That's correct.
Q. That's seven years after you left Abbott?
A. Yes.
Q. And sir, Ritonavir or Norvir -- correct?
A. Norvir.
Q. -- was approved by the U.S. Food and Drug Administration in 1996, correct?
A. I don't recall the date of approval of Norvir.
Q. If you wanted to find that out, where would you look?
A. Oh, the Orange Book.
MR. CURRAN: Sir, may I approach the witness to show him a copy of the Orange Book?
JUDGE CHAPPELL: Yes.
MR. CURRAN: Thank you.
BY MR. CURRAN:
Q. Sir, you know how to read the Orange Book as well as I do, correct?
A. Yes.
Q. Sir, Ritonavir was approved by the U.S. Food and Drug Administration in 1996, correct?
A. Yes, sir.
Q. That's 14 -- that's 12 years after you left Abbott, correct?
A. Yes, it is.

Q. And sir, Hytrin was approved by the U.S. Food and Drug Administration in 1987, correct?

A. I believe that's correct, yes, for some of its indications, yes.

Q. The others were later, correct?

A. The others were later.

Q. All right. So, we've got Hytrin 1987, Biaxin 1991 and Norvir 1996, and those are all drugs that resulted from programs you initiated at Abbott?

A. Yes, they were.

Q. How is it it takes that long for drugs to go from the initiation of a program to U.S. Food and Drug approval?

A. Well, each of those three are slightly different examples. In the instance of Biaxin, we licensed the drug and then had to do some -- a fair amount of what we referred to as preclinical development in terms of developing the microbiology on that drug, and there was actually some debate within the company as to whether it had the sort of profile that we wanted initially. So, we had to demonstrate that.

Then the clinical trials just took -- you know, took a while, and then the -- I don't recall how long the FDA review process is, but that's typically -- back

in those days particularly -- things have been expedited in recent years, as I'm sure you know -- but back then, a two or three-year review cycle was not unusual. I don't recall how long Biaxin's was.

In the instance of Hytrin, the -- we actually assembled the NDA, and I don't remember whether we filed it or not, but I know that all of it was assembled under -- you know, when I was there, and -- for hypertension, and then we also -- one of the things that I felt best about was recognizing that Hytrin, which was an alpha-1 antagonist, somewhat similar to Pfizer's Prazocin at the time but had some pharmacological advantages, and I thought that it might be useful for benign prostatic hypertrophy and actually started that program for that, but that shows you how long it takes.

But the hypertension indication, we completed all the pharmacology and all the clinical studies while I was there and then filed the -- filed the NDA either when I was there or within a year or so after I left, I believe, and the drug was reviewed for a couple of years and approved.

In the instance of Norvir or Ritonavir, that's even a longer cycle, because that program actually arose out of our attempt to find an inhibitor for an

enzyme called renin, R E N I N, and in the -- renin is an enzyme in the same general biochemical category as is the HIV protease, which is what Ritonavir inhibits, and so we realized that as AIDS became a problem in the early eighties and we realized what we had, and we initiated that program.

Now, that program took so long because very, very little was known about the HIV protease enzyme back in the early eighties, and we had to actually do some of the initial biochemistry and crystallography on that enzyme that ultimately led to the design. That was one of the -- it's a very interesting drug, because it was -- I like to talk about it, so I apologize, but it -- you know, I -- one of the things that I set up there was what we referred to as computer-assisted molecular design or so-called rational drug design, and Abbott was one of the leaders in that area, and this program developed specifically from that. It was actually the first example coming from that, the rational drug design paradigm.

So, to answer your question, I mean, you're asking why it took so long. I mean, there was a huge amount of work to define the active site of the HIV protease inhibitor and to develop chemicals that interfered with that active site. And so it was a long

program.

Q. Sir, isn't it unfair and totally inaccurate for you to say you started those programs?

A. I don't think so at all. Well, it depends on how you define "unfair." It was started under my supervision. The -- interestingly, the three that you happened to cite I think anybody there would tell you that I played a very significant role in driving, because Biaxin was licensed in -- almost by accident. I saw the data -- well, I mean, you've asked me the question, I'll try to answer the question.

Q. Do you recall what the question was?

A. Yes, I do, and I'm trying to answer it. I realize it's an unusually long-winded answer, but -- I apologize for that, but you've asked the question.

The answer is yes in terms of did I play an -- you know, a very active role in that, and unusually so for a person in my position, and the reason for that was that Biaxin came in under a program where Abbott, because its major drug was erythromycin, Abbott tried to license up virtually every macrolide antibiotic that came long, more defensively than offensively, and my microbiology chief, a woman named Prabha Fernandes, showed me the data and said we can't -- we really have to develop this drug. This thing looks good.

And I became quite actively involved in looking at that program and actually championed it -- championed the in-licensing of that drug, because they were not willing to -- the company initially was not willing to pay what Taisho wanted.

Q. Sir, my question was, isn't it unfair and totally inaccurate of you to say that you started those programs?

A. And I said no.

Q. Okay. Sir, at your deposition -- do you still have your -- feel free to refer to the copy if you have it there.

A. I do.

Q. But do you recall on page -- recorded on page 146, I asked:

"QUESTION: Did you start the programs that led to several marketed drugs, including Hytrin, Biaxin and Ritonavir?"

Then you began a long answer by stating, "Again, 'start the programs'?" And then you went on over at page 147 to state, "Those programs in a fair sense were initiated by various people who were under my aegis. You know, for instance, the renin program was -- if I were to name a person who started it, it was Jake Plattner. The Ritonavir program, if I named a

person who started it, it was Jonathan Greer. The Hytrin program, if I named a person who started it, it was Jaroslav Kincl, and so on. If I wanted to name the person who started the Biaxin program, it was Prabha Fernendes.

"So, it would be totally --" I'm sorry, "So, it would be unfair of me and totally inaccurate of me to say that I started those programs."

Did I read that correctly?

A. Yes, you did.

Q. Okay. Sir, in any event, it takes a long time to develop drugs to be approved by the U.S. Food and Drug Administration, correct?

A. Yes, it does.

Q. It takes a long time in development, correct?

A. Yes.

Q. It takes a long time for regulatory clearance, correct?

A. Yes.

Q. And I believe you acknowledged yesterday to Ms. Shores that clinical studies can take a lot of money, correct?

A. Yes.

Q. Take a lot of resources?

A. Yes.

Q. Sir, do pharmaceutical companies sometimes use consultants to help them with clinical studies?

A. Yes.

Q. Do you know what a CRO is?

A. Yes.

Q. What's a CRO?

A. Contract research organization.

Q. And what do they do in the context of clinical studies?

A. Well, I'm -- what they are supposed to do, what they are purported to do and what they often do quite poorly, unfortunately, is do what -- they conduct various elements and sometimes even the entire program of clinical development or other types of research. I mean, it's contract research organization. I think in the context you're asking me, you're asking me about clinical trials. They can do toxicology, they can do almost anything.

Q. They specialize in those fields, correct?

A. They purport to specialize in those fields, yes.

Q. All right. Is it your testimony that all of these CROs do their work quite poorly?

A. No.

Q. Some are good, some are bad?

A. Some are good, some are bad, that's correct.
Q. Just like doctors, right?
A. Fair comment, yes.
Q. Sir, can you name any CROs that you consider to be reputable?
A. Oh, Parexel is one that, you know, is I think a well-regarded CRO.
Q. Any others?
A. Oh, I'm trying to think of some that I've worked with that, you know, I don't want to just throw out names of CROs and, you know, and say they're good or bad. I'd really rather not comment on CROs that are good or bad.
Q. What if I drop the "reputable" adjective, can you name other CROs?
A. Well, Phoenix is a CRO.
Q. Okay. Any others that come to mind?
A. Gee, oh, there's one called Theratec that we've used the -- I think if you -- if you give me a moment, I can think of a bunch of them, but they are just not -- my mind is not thinking of them.
Q. Sir, isn't it fair to say that pharmaceutical companies frequently use CROs in conducting clinical studies?
A. Yes.

Q. It's not unusual, right?

A. No, particularly smaller pharmaceutical companies.

Q. Sir, isn't it also fair to say that the potential value of a pharmaceutical product increases as it succeeds in moving through the clinical study phases and moves toward FDA approval?

A. No, actually, you know, my -- the one business paper that I've written in my life actually speaks to that point, and in my experience, that is not the case. So, I mean, if you would like me to elaborate, I'll be happy to do that.

Q. No, I've read the article.

A. Okay.

Q. So, it's your testimony that advancing through the phases from, say, phase I to phase II to phase III, that's a bad thing, right?

A. No, I'm not saying that, and you know I'm not saying that. I'm saying that --

Q. Okay, let me restate the question.

As a pharmaceutical product moves through the phases, phase I, phase II, phase III, its value goes down?

A. I'm not saying that either.

Q. Okay. All right, sir, let's talk about value

for a minute. Are you familiar with the term "NPV"?

A. Yes.

Q. What's that mean?

A. Net present value.

Q. Sir, net present value is a methodology for valuing something, correct, in the vaguest terms?

A. In the vaguest terms, yes.

Q. To be more precise, it involves discounting anticipated cash flows, correct?

A. Yes.

Q. Sir, it's often used in valuation, correct?

A. For valuations of some things.

Q. Sir, it's something that financial -- that people doing financial analyses like to see, correct?

A. Some people doing some financial analyses like to see it.

Q. Well, generally they do, right?

A. No.

Q. Sir, you use net present value analyses, correct?

A. Sometimes.

Q. And NPVs are very standard parameters, correct?

A. I'm not sure what that means.

Q. All right, let me reask the question.

Sir, an NPV is a very standard parameter that

people doing financial analyses like to see, correct?

A. Well, as I said, sometimes they do, yes. And sometimes -- and it is a standard parameter if that's what you're asking me.

Q. Well, okay, let's break it down in two parts. It's a standard parameter, correct?

A. Yes.

Q. And it's something that people doing financial analyses like to see, correct?

A. Sometimes.

Q. Sir, at your deposition, do you remember our discussion about your consumer food product, the Lox Box?

A. Yes, I do.

Q. And this is a product developed by CoreTechs, correct?

A. Well, no. It's a separate company that was -- that we formed to market the Lox Box. So, it's not a CoreTechs product.

Q. All right, it's one of the products that you invented, correct?

A. Yes.

Q. And it's one of the products that you market and sell, correct?

A. Yes.

Q. And it's a device that you put in your refrigerator or freezer, and it converts salmon into lox, correct?

A. That's right.

Q. Okay. And sir, when you were trying to determine the value of that product, you performed an NPV, correct?

A. We performed an NPV analysis on the Lox Box. That was not what we did to determine its value.

Q. Okay. Well, did you do that just for fun? Okay, let me withdraw the question.

A. It's a very easy calculation to do, and so, you know, there's no harm in doing it.

Q. Okay, NPV value -- NPV calculations are very, very easy to do, correct?

A. I don't know if it -- you have to say "very, very easy." I mean, you know, you -- it's -- if you happen to have an Excel program, it's a very easy thing to do, and it's probably not a particularly difficult calculation to do, you know, without, you know, modern computer technology.

Q. But you've got at your office, your home office, what you need to do an NPV analysis, correct?

A. At all of my offices.

Q. Okay. Sir, you didn't do an NPV analysis on

Niacor-SR, correct?

A. That's correct.

Q. And sir, you didn't do an NPV analysis on Klor Con 8, correct?

A. On what, I'm sorry?

Q. Klor Con 8.

A. Klor Con 8?

Q. Yes, Klor Con 8.

A. I am drawing a blank on Klor Con 8.

Q. You don't remember doing an NPV analysis of Klor Con 8, do you?

A. No, I don't.

Q. Do you remember doing an NPV analysis on Klor Con 10?

A. No, I didn't do one on Klor Con 10 either.

JUDGE CHAPPELL: Mr. Curran, were you saying the number 8 or the letter A?

MR. CURRAN: The number 8, Klor Con 8.

JUDGE CHAPPELL: Sir, does that change your answer?

THE WITNESS: No, sir.

JUDGE CHAPPELL: You may proceed.

BY MR. CURRAN:

Q. And the follow-up question was Klor Con 10, and you didn't do an NPV on that, right?

A. No, that's right.

Q. And you didn't do an NPV analysis on Klor Con M20, did you?

A. No.

Q. And you didn't do an NPV analysis on pentoxifylline, did you?

A. Pentoxifylline, no.

Q. And you didn't do an NPV analysis on Prevalite, did you?

A. No.

Q. In fact, you didn't use any valuation methodology on any of those products, did you?

A. I don't think it was part of my -- the area of expertise that I was asked to opine upon to do valuations, to do financial analyses on any of these products.

Q. So, your answer is, you didn't do any valuation methodology on any of those products, correct?

A. No, and I certainly wouldn't have used NPV had I had.

Q. Sir, did you do any valuation analysis on the production rights that were given to Schering-Plough by Upsher-Smith in the June 17, 1997 licensing agreement?

A. I'm sorry, the production rights?

Q. Yes.

A. I'm not sure what you're referring to, sir.

Q. Sir, what did Schering-Plough get in the June 17, 1997 agreement?

A. They got rights to Niacor-SR in the non-NAFTA territories. They got rights to three generic pharmaceuticals in I believe it was non-NAFTA territories, and one of those was -- existed in three different dosages, the potassium chloride product.

Q. Is that all they got?

A. Well, I know there was another part to this agreement which I've not been asked to opine on.

Q. Are you aware of any production rights or supply rights that Schering-Plough got in that June 17, 1997 agreement?

A. I don't recall those.

Q. In forming your opinions in this case, did you take into account any production rights or supply rights provided by Upsher-Smith to Schering-Plough in that agreement?

A. No.

Q. Sir, I want to ask you a hypothetical question. If Upsher-Smith were to agree to manufacture Claritin for Schering-Plough at cost, how would that affect Upsher-Smith's business operations?

A. I'm sorry, if Upsher-Smith were to be given the

opportunity to manufacture Claritin --

Q. No, no, not the opportunity. Let me restate this.

If Upsher-Smith were obligated to manufacture Claritin for Schering-Plough at cost and at whatever quantity Schering-Plough wanted, what impact would that have on Upsher-Smith?

A. I think that that in isolation is difficult to answer, because there are a multitude of factors that could enter into that. For instance, were Upsher-Smith to be put in that position but were it to have a -- were it to have the opportunity to, if you will, I think you said sell at cost Claritin, but then had a manufacturing facility that it could then use for a vast panoply of other pharmaceutical agents, it could be a very good deal. So, I mean, you're giving me insufficient information to comment upon whether that was or was not a -- you know, a viable and effective business opportunity for Upsher.

Q. Sir, when a company sells something at cost or provides a service at cost, it's not a very profitable enterprise, is it?

A. As I said, taken in isolation like that, it's -- it's difficult to answer.

Q. This is a separate question, brand new

question.

A. Okay.

Q. If you manufacture something and sell it at cost or you provide a service at cost, that's not a very profitable enterprise, is it?

A. Well, by definition, something done at cost, there is no -- there is no net gain, so that itself is not profitable, but there are a --

Q. Okay, sir.

A. -- multitude of circumstances where that is a very profitable endeavor.

Q. All right. Sir, if Upsher-Smith were obligated to manufacture Claritin in any amount Schering-Plough wished, that might squeeze out Upsher-Smith's production of other pharmaceutical products, correct?

A. I think the operative word there is "might."

Q. And what's the answer?

A. It might, yes.

Q. Sir, that's something you didn't consider in analyzing the June 17th, 1997 agreement, correct?

A. Whether Upsher-Smith was going to have the opportunity to manufacture Claritin for Schering-Plough? I think Schering-Plough would have been out of their bloody mind.

Q. Okay, let me ask the question a little

differently. I don't want anybody to be out of their bloody mind here.

Sir, if Upsher-Smith was obligated under the June 17th, 1997 agreement to manufacture anything at cost and in the quantities desired by Schering-Plough, that might squeeze out other products from Upsher-Smith's production lines, correct?

A. As I said, sir, I'm really not trying to be, you know, evasive or cute with you. The word is "might," and it might be bad, it might squeeze out things, it might not. I mean, but if you want me to -- if you're saying "might," that is one of the alternatives. It might have squeezed out other opportunities for Upsher-Smith.

Q. And that's something you didn't consider in analyzing the June 17th, 1997 agreement.

A. No.

Q. Sir, sitting here today, you don't know if Niacor-SR is worth zero, $10 million or $100 million, do you?

A. You've given me the choice of zero, $10 million or $100 million? Those are the three choices you're giving me?

Q. Yeah.

A. I would say it's neither of those.

Q. Sir, you don't know if Klor Con 8 is worth zero, $10 million or $100 million, do you?

A. Once again, I would say it's -- in my opinion it would be neither of those.

Q. And sir, as to Klor Con 10, sitting here today, you don't know if that's worth zero, $10 million or $100 million, do you?

A. The same answer I'm afraid, sir.

Q. And sir, Upsher-Smith's pentoxifylline product, sitting here today, you don't know whether that's worth zero, $10 million or $100 million, do you?

A. As I said, I can't choose between those three. I believe it is -- none of those three would be -- would be responsive to your question.

Q. And sir, sitting here today, you don't know if Upsher-Smith's Prevalite product is worth zero, $10 million or $100 million, do you?

A. The same answer, sir.

Q. Sir, sitting here today, you don't know whether Upsher-Smith's Klor Con M20 is worth zero, $10 million or $100 million, do you?

A. Same answer.

Q. Sir, you didn't do any quantitative analysis of the value of any of those products, did you?

A. That's correct.

MR. CURRAN: Your Honor, I have some books of exhibits I'd like to hand out at this time.

JUDGE CHAPPELL: Have they been provided to complaint counsel?

MR. CURRAN: I'm doing that right now.

MR. SILBER: Thank you.

MR. CURRAN: Your Honor, may I approach the witness and Your Honor?

JUDGE CHAPPELL: Yes. Do you intend to introduce these into evidence?

MR. CURRAN: Eventually I do, Your Honor.

THE WITNESS: Excuse me, Mr. Curran, do you want these back?

MR. CURRAN: Sure.

THE WITNESS: Okay, thank you.

MR. CURRAN: Do you want me to take everything back but your deposition?

THE WITNESS: Whatever we don't need.

MR. CURRAN: Why don't we leave your deposition there, we might need it again.

JUDGE CHAPPELL: Mr. Curran, do you want to give complaint counsel a few minutes to review these for any objection, or do you have a strategic reason not to?

MR. CURRAN: No, Your Honor, they certainly may

review them. They are all --

THE WITNESS: Excuse me, Mr. Curran, you took my report. Oh, I have it here, I'm sorry, sir.

MR. CURRAN: Certainly, Your Honor, we can take a moment to see if complaint counsel has an objection to any of these materials.

BY MR. CURRAN:

Q. Dr. Levy, if I can ask you to hold off, I am going to be taking you through these seriatim.

A. Okay, sure.

MR. SILBER: Your Honor, we have no objection to the admission of these documents.

JUDGE CHAPPELL: Thank you. If he offers one, then I will need to know at that time, because I don't think from what he said he's going to introduce the whole binder.

MR. SILBER: Yes, Your Honor.

JUDGE CHAPPELL: Thank you, Mr. Silber.

You may proceed, Mr. Curran.

MR. CURRAN: Thank you, Your Honor.

BY MR. CURRAN:

Q. Dr. Levy, you're familiar with the company Kos, correct?

A. Yes, I know of it. I'm not -- I mean, I am -- I'm not an expert on Kos.

Q. You know -- in fact, you testified yesterday that their lead product is Niaspan, correct?

A. Yes.

Q. And that's a sustained release niacin product, correct?

A. Yes.

Q. And that's a cholesterol-fighting drug, correct?

A. Yes.

Q. And its sales last year were approximately $100 million, correct?

A. That's what you showed me in the IMS data, yes.

Q. But you trust the IMS data, correct?

A. Yes, yes.

Q. Sir, what was Kos' market capitalization in March 1997?

A. In March of 1997? I don't recall, sir.

Q. Do you have any ballpark?

A. No, I don't have any ballpark.

Q. Sir, I'd like to direct your attention to the document under the first tab.

A. Okay.

Q. And for the record, that is USX 21. Now, Dr. Levy, you'll see --

Your Honor, at this time I'd like to move for

the admission of USX 21.

JUDGE CHAPPELL: Any objection?

MR. SILBER: No objection, Your Honor.

JUDGE CHAPPELL: Schering?

MS. SHORES: No objection.

JUDGE CHAPPELL: What was that exhibit number again?

MR. CURRAN: USX 21.

JUDGE CHAPPELL: USX 21 is admitted.

(USX Exhibit Number 21 was admitted into evidence.)

BY MR. CURRAN:

Q. Dr. Levy, this is a prospectus for Kos Pharmaceuticals, Inc., correct?

A. Yes, it looks like an offering memorandum.

JUDGE CHAPPELL: Do we have a technical problem at respondents' table?

MS. SHORES: We solved it, Your Honor.

JUDGE CHAPPELL: Okay. You may proceed.

MR. CURRAN: Thank you, Your Honor.

BY MR. CURRAN:

Q. Dr. Levy, you've looked at prospectuses before, correct?

A. Yes, I have.

Q. Or is it prospecti?

A. I don't know. I think in this country it's probably prospectuses, don't you think?

Q. Sir, I want to refer your attention to page 17, I think this is the quickest way to proceed.

A. Okay.

Q. Do you see that page?

A. Yes, sir.

Q. Okay. Do you see the chart there where it lists existing shareholder and new investors?

A. Yes, I do.

Q. Okay. Sir, this indicates that the public offering being made through this prospectus is for 29 percent of Kos' outstanding shares, correct? And please, take a moment to look at the chart.

A. Yes, I believe that's correct, sir. I don't want to take your time -- I mean, that makes sense, yes, sir.

Q. Okay. Sir, back to the front page, you see that the Kos stock was being offered to the public at $15 a share, correct?

A. Yes, I do.

Q. And it was therefore raising $62 million and change, correct?

A. Well, that's what it was hoping to raise in this -- you know, with this offering memorandum, yes,

sir.

Q. Well, it did raise that amount, in fact, correct?

A. I don't recall that. I don't know.

Q. Okay. Sir, this $62 million and change, that's for 29 percent of the company, correct?

A. Yes.

Q. Okay. So, ballpark, the market capitalization of Kos was about three times that and a little bit more, right?

A. Yes.

Q. In the neighborhood of $200 million?

A. Yes, sir.

Q. Okay. And this is in March of 1997, correct?

A. Yes.

Q. Sir, I'd like to ask you to look at tab 2.

A. Okay.

Q. Sir, this is a commentary on Kos Pharmaceuticals dated May 2nd, 1997 by the Cowen Securities Company, correct?

A. Yes, it is.

MR. CURRAN: Your Honor, I move for the admission of this document into evidence. This is SPX 225, and let me clarify that. We're moving for its admission not as to the truth of the predictions of

Cowen but as to what was being said by stock analysts at this time.

JUDGE CHAPPELL: Any objection?

MR. SILBER: No objection, Your Honor.

MS. SHORES: No objection, Your Honor.

JUDGE CHAPPELL: SPX 225 is admitted.

(SPX Exhibit Number 225 was admitted into evidence.)

BY MR. CURRAN:

Q. Dr. Levy, the first page of this document indicates that Cowen was rating Kos a strong buy, correct?

A. Yes, sir.

Q. And it had a price target of $35 in a 12 to 18-month range, correct?

A. Yes, sir.

Q. Sir, I'd like to ask you to flip to tab 3. Sir, tab 3 is a commentary on Kos Pharmaceuticals' stock by Salomon Brothers, correct?

A. Yes, sir. Yes.

MR. CURRAN: Your Honor, I move for the admission into evidence of SPX 226 on the same grounds as the prior exhibit.

JUDGE CHAPPELL: Any objection?

MR. SILBER: No objection, Your Honor.

MS. SHORES: No objection, Your Honor.

JUDGE CHAPPELL: SPX 226 is admitted.

(SPX Exhibit Number 226 was admitted into evidence.)

MR. CURRAN: Thank you, Your Honor.

BY MR. CURRAN:

Q. Dr. Levy, this is dated May 9, 1997, correct?

A. Yes, sir.

Q. And Salomon Brothers was characterizing the Kos Pharmaceuticals stock as a buy, correct?

A. Yes, sir.

Q. Sir, I'd like to direct your attention to the third bullet point on that page. Do you see where it states, "We estimate that sales of $220 million for Niaspan in the year 2000 will result in earnings per share of $3.50"?

A. Yes, I see that.

Q. Do you see the next sentence where it says, "A multiple of 25 times earnings would result in a share price of $85-$90 in three years"?

A. Yes, I see that.

Q. Sir, I'd like to ask you to flip to tab 4. Sir, under tab 4, there's a May 12, 1997 commentary on Kos Pharmaceuticals by the Dillon Read securities company, correct?

A. Yes, I see that.

MR. CURRAN: Your Honor, I move for the admission of SPX 224, this document, to be admitted into evidence on the same grounds as the prior two documents.

JUDGE CHAPPELL: Any objection?

MR. SILBER: No objection, Your Honor.

MS. SHORES: No objection, Your Honor.

JUDGE CHAPPELL: SPX 224 is admitted.

(SPX Exhibit Number 224 was admitted into evidence.)

BY MR. CURRAN:

Q. Now, Dr. Levy, this -- Dillon Read at this time was rating the Kos Pharmaceuticals stock as a buy, correct?

A. Yes, sir.

Q. And it's indicating that the price on this date, May 12, 1997, was $25 per share, correct?

A. Yes, I think so, sir, yes.

Q. Let's do a little math. So, as of this point in time, $25 -- I think we established before that there were about -- approximately 14 million shares outstanding. Is that correct?

A. I don't recall that, sir, but -- I just haven't remembered that number.

Q. Okay. Well, let's make sure we get this right. Let's flip back to tab 1.

A. Okay.

Q. And page 17 there, where we have the chart.

A. Okay, I see it, sir.

Q. Okay. So, we have -- let's run --

A. I don't want to nit-pick, but that -- that assumes that the IPO was sold out, but I presume that you're telling me that it was.

Q. Okay, let's continue on that assumption.

A. Okay, that's fine.

Q. Okay, so we've got 14 million shares and -- a little bit more than that at $25 a share. Sir, that leads to a market cap north of $300 million, correct?

A. Yes, it does.

Q. Sir, I'd like to direct your attention to tab 5. Sir, that's a document showing the stock price, high, low, open, close, of Kos Pharmaceuticals on June 17, 1997, correct?

A. Yes.

Q. And sir, it indicates that the Kos Pharmaceuticals stock closed at $29.50 that day, correct?

A. Yes, sir.

Q. That's roughly double what the IPO was offered

at, correct?

A. Yes.

Q. So, using some logic here, okay, if it was worth in the neighborhood of $200 million market cap, total market cap, back in March, at this point it's in the neighborhood of $400 million, correct?

A. Yes, sir.

Q. Sir, I'd like to direct your attention to the tab -- the document under tab 6. Sir, do you see -- that document shows the price of Kos stock on November 11, 1997, correct?

A. Yes.

Q. And there the price had jumped about a buck, right, to $30-$31 a share at the close?

A. Yes.

Q. When I say "jumped a buck," I'm comparing it to the June 17.

A. Right, right.

Q. Okay, sir, I'd like to direct your attention to the document under tab 7. Sir, that document shows the price of Kos Pharmaceuticals' stock on November 12, 1997, correct?

A. Yes, sir.

Q. Okay, that's one day later than the document we were just looking at under tab 6, correct?

A. Yes.
Q. That was a bad day for Kos' stock, wasn't it?
A. It looks like it, yes, sir.
Q. In fact, on that day, sir, from a high of $30.25 a share, Kos closed at $16.56 a share, correct?
A. Yes, sir.
Q. And that's a fall in about half, correct?
A. Yes.
Q. Do you know why the stock price fell that day?
A. I don't -- the answer is no, I don't know why. I have suspicions why.
Q. In performing your analysis in connection with this case, did you consider the fortunes of the Kos stock price?
A. No.
Q. Sir, I'd like to direct your attention to the document under tab 8. Sir, that's an article taken from the New York Times on November 13, 1997, correct?
A. Yes, sir.
Q. And sir, this document indicates that Kos Pharmaceuticals had released first quarter results on the prior day, correct?
A. Yes, sir.
Q. And it further indicates that those results showed that sales of Niaspan were not rising as fast as

analysts expected, correct?

A. Yes, sir.

Q. And it further indicates that the Kos Pharmaceuticals stock fell after that news was released by the company, correct?

A. Yes, sir.

Q. Sir, I'd like to direct your attention to the document under tab 9. Sir, that's a graph showing the market capitalization of the Kos Pharmaceuticals stock from roughly March of 1997 to September of 1998, correct?

A. Yes, sir.

Q. Sir, this indicates that between March of '97 and roughly September of '97, the Kos stock and therefore its market capitalization were rising, correct?

A. I'm sorry, would you say that again, please, sir?

Q. Sure. This graph indicates that the Kos stock price and therefore its market capitalization were increasing from March of 1997 to September of 1997, correct?

A. Yes, sir.

Q. And then, in the remainder of '97, there was a precipitous drop in the stock price and the market

capitalization of Kos, correct?

A. Yes, sir.

Q. In fact, looking at this graph, the stock price appears to have fallen by about half, correct?

A. Yes, sir.

Q. Okay. Sir, we're through with that binder.

Your Honor, if you'd like, I'll collect yours?

JUDGE CHAPPELL: Now or later, your choice.

MR. CURRAN: Your Honor, my colleagues remind me that perhaps I ought to move for the admission into evidence of the documents under tabs 5, 6, 7 and 8, and we will mark those for identification and present them to the court reporter, so at this time I ask -- I move for the admission of those documents on the grounds that they are tabulations and compilations of stock price.

JUDGE CHAPPELL: You can't do it until you have an exhibit number. I can't do it by tab number, Mr. Curran.

MR. CURRAN: Very good, Your Honor. On a break, I'll have those marked and move at that time for the admission.

JUDGE CHAPPELL: Okay.

MR. CURRAN: Thank you, Your Honor.

BY MR. CURRAN:

Q. Sir, I want to talk for a moment about the clinical trials on Niacor-SR. Sir, Upsher-Smith conducted clinical trials on Niacor-SR, correct?

A. I believe so, yes.

Q. What's your understanding as to how many clinical trials were conducted?

A. They -- they say they conducted two phase III clinical trials. They also attempted to conduct a pharmacokinetic study that never seemed to fulfill the needs of the Food and Drug Administration.

Q. Any other studies, any other clinical studies?

A. I'm not aware of any other studies that they -- that they conducted, because I've not seen any results on them. You know, there were two other studies that were open-label studies that they say they conducted, but I've seen no data, just seen nothing on them.

Q. In reaching your conclusions in this case, did you give consideration to any follow-on studies?

A. Sir, in reaching the -- most of the conclusions in this case, I think as I testified, I tried to look at that information that had been presented to Schering when it made its decision, and that's what I focused upon. Subsequent to -- and focused on in writing my report. Subsequent to that, I have had the occasion to see other documents as well, but the -- I think that,

as I understand my charge, if you will, it was to try to understand whether the payment that was made by Schering to Upsher was -- could reasonably have been expected to be for the products that were licensed, and so I looked at what Schering had the opportunity to look at in making that decision.

Q. Sir, you don't know what Schering knew about the status of Upsher-Smith's clinical studies as a result of negotiations between those two companies in May and June of 1997, do you?

A. I don't want to be presumptuous. I have read the testimony, I have looked at I believe all the documents that Schering had seen, and I have read the testimony of the single individual who seemed to be involved with all of the evaluation of that product, both of his depositions and all the exhibits associated with those two depositions. So, I think I can answer that I do know.

Q. So, is it your testimony here today that you believe you know everything that was said between Schering-Plough representatives and Upsher-Smith representatives in negotiations leading up to June 17, 1997? Is that your testimony?

A. The reason I'm hesitating is to try to answer you honestly, sir --

Q. Well, you can take as long as you want, and I certainly want an honest answer.

A. This goes beyond my area of expertise. It is my opinion, in fact, conversations ensued between members of the two companies that were not brought forth in discovery, most likely between the attorneys, which would not have been discoverable, but I have no idea -- you're asking my opinion, which is hardly an expert opinion, but I'm trying to respond to you. You're asking me whether I knew about every communication that went on between those two companies, and I would say I probably don't.

Q. Okay. Sir, the FDA requires as one of the major elements for the registration in the U.S. of a new branded pharmaceutical product the conduct of two so-called pivotal clinical trials, correct?

A. Usually, yes.

Q. And sir, pivotal trials are well-controlled studies in a substantial population of patients that demonstrate convincingly both the safety and efficacy of the pharmaceutical product, correct?

A. Yes.

Q. And at the time of the Schering-Upsher agreement, Upsher had finished two clinical trials that it hoped the FDA would consider as pivotal, correct?

A. I think the operative word there is that they "hoped" the FDA would consider pivotal.

Q. Sir, do you have any basis in the record -- are you aware of any basis in the record to support the conclusion that the FDA did not consider Upsher's pivotal studies as pivotal?

A. I'm not sure what you mean by "basis in the record," sir.

Q. Yeah, have you seen any documents indicating that folks at the FDA had a problem with those studies sufficient that they wouldn't accept them as pivotal studies?

A. The answer to that is --

Q. Well, are you aware of any communications, any documents indicating the FDA --

A. No.

Q. -- representatives had that position?

A. No.

Q. Okay. Now, sir, Schering's stated plan was to use the data in Upsher-Smith's NDA to support applications for registration of Niacor-SR in the EU, correct?

A. Yes, sir.

Q. Now, we established yesterday, didn't we, that U.S. FDA approval is not a prerequisite to foreign

regulatory approval of a pharmaceutical product, correct?

A. Yes, sir.

Q. But it's helpful to have the data from the U.S. clinical studies to support a foreign regulatory application, correct?

A. Yes, sir.

Q. Now, sir, in your direct examination, you expressed some concern about a shift on the part of Upsher-Smith from a new drug application strategy to an abbreviated new drug application strategy, correct?

A. Yes, sir.

Q. And you stated in words to the effect that that change would be harmful to Schering, correct?

A. I don't think I used the term "harmful." I think I -- I think I used the term "anathema."

Q. Can you say that word again?

A. Anathema.

Q. Anathema?

A. Anathema. They wouldn't have liked it.

Q. It would have been a bad thing. Is that one word or two, anathema?

A. It's one word.

Q. One word, okay. And the reason for that is because an ANDA doesn't need the same clinical data

support as an NDA, correct?

A. No, that's not correct. I mean, if you're asking me why would that strategy have been unpopular -- and the reason I used the term I did, because I think that I was trying to say that it was -- that it was -- you used the term "harmful," I just used the word "anathema," because you seemed to be denigrating my use of the word "anathema."

Q. I didn't mean that at all, sir, did not.

A. But I think that it would have been an exceedingly unpopular move on the part of Upsher in the eyes of Schering-Plough at that time.

Q. Sir, do you have an understanding as to when, if ever, Upsher-Smith switched from an NDA strategy on Niacor-SR to an ANDA strategy?

A. From their internal meeting minutes, I believe I do, sir, yes.

Q. What internal meeting minutes are you referring to?

A. Their -- I don't know how to -- I don't know how to characterize them further than the fact that they seem to be -- they were -- they were one page or in some cases I think they were two-page summaries of meetings that occurred seemingly monthly where the various matters concerning the Niacor project were

discussed, I believe, and in -- among the documents that I was able to see were the minutes of those meetings, that -- I don't know how you further characterize them, sir, as --

Q. Did you cite those documents in your report?

A. I believe I did, yes, sir.

Q. Sir, do you have your report there?

A. No, I don't, no. May I get it from my briefcase or -- I have a copy here.

Q. Yes, you may if you have it handy, or I can --

A. The one that I have with me is the one that Ms. Shores got a copy of during my deposition, and so it -- you know, it has -- it has no more notes in it now than it did then. It hasn't been changed since then, but you all have a copy of that. So, I'd rather use that one, if I may, since I have dog-eared it or whatever.

Q. Well, Mr. Silber has just handed me a clean copy, and for this purpose, is that satisfactory?

A. That's fine.

MR. CURRAN: Your Honor, may I approach the witness?

JUDGE CHAPPELL: Yes.

THE WITNESS: Thank you.

BY MR. CURRAN:

Q. Sir, can you please refer to page 31 of your

report?

A. Yes, sir.

Q. On that page, is that where you cite the meeting minutes that you referred to?

A. I'm not sure what these references are. I believe they are the references that I'm referring to, sir. I -- you know, I don't -- I don't recall what, for instance, USL 12581 is, but I -- but I think that they are the documents to which I'm referring.

Q. Okay, I'd like to provide you with those documents, if I may.

A. Okay.

MR. CURRAN: Your Honor, may I approach the witness and Your Honor?

JUDGE CHAPPELL: Yes, you may.

BY MR. CURRAN:

Q. Dr. Levy, feel free to refer to the documents under tabs 1, 2 and 3. For the record, I will indicate that the document under tab 1 has a Bates number of USL 12581; the document under tab 2 has the Bates number USL 12580; and the document under tab 3 has the Bates number USL 12579.

Dr. Levy, are those the documents that you relied upon and cited in your report?

A. Yes.

Q. Sir, what's your understanding as to what these documents are?

A. Sir, it's my understanding that these were summaries or minutes of meetings within Upsher-Smith to discuss the Niacor-SR project.

Q. Who do you believe attended the meetings reflected in these documents?

A. I have no idea, sir. They were not -- I don't believe that the attendees were listed here. You're asking me whom I believe attended it. I -- I -- it would be a guess. I don't have any way of knowing.

Q. What's your understanding as to who prepared these documents?

A. I have no idea on that either, sir.

Q. What's your understanding as to the purpose for which these documents were prepared?

A. I think to memorialize discussions and conclusions and action plans that were formed in whatever these meetings were.

Q. That's a guess, right?

A. I don't think it's a guess. I think it's what these documents seem to do.

MR. SILBER: Objection, Your Honor. They've taken about three pages out of a long document, and these are some of the pages Dr. Levy cites in his

report, but I believe the first page of this document has some type of heading on it which indicates what these documents are, and Dr. Levy probably reviewed that document, and I think it would be fair if he had the full document in front of him rather than just selected pages.

MR. CURRAN: Let me address that, Your Honor, if I may. These are the documents, the pages in full, cited by Dr. Levy in his report in footnotes 49, 50 and 51.

MR. SILBER: I believe that's what I also stated, Your Honor, but I am also aware that Dr. Levy had the complete document when he looked at it.

MR. CURRAN: Your Honor, I would suggest that that's ample ground for redirect.

JUDGE CHAPPELL: What's your legal basis for the objection?

MR. SILBER: Well --

JUDGE CHAPPELL: Not fair? What --

MR. SILBER: I'm not sure if that's a real strong legal basis, Your Honor.

JUDGE CHAPPELL: I don't either, but go ahead.

MR. SILBER: I'm just saying that I think it is unfair to have him review this document with just these couple pages when there is other information in this

document he may have relied upon in interpreting this information.

JUDGE CHAPPELL: I think I'm going to overrule the objection. I think Dr. Levy's demonstrated he can handle the questions. If he doesn't have what he needs, he can state that for the record.

MR. SILBER: Okay, thank you, Your Honor.

JUDGE CHAPPELL: And also, as Mr. Curran said, if you think something's been unfair, that's why we have redirect.

MR. SILBER: Very well, Your Honor.

BY MR. CURRAN:

Q. Dr. Levy, I'd like to refer your attention to the document under tab 1.

A. Yes.

Q. Do you believe that that's one page of a multipage document?

A. This is the page I cited because this is the page that had information on it that was germane to my report.

Q. Okay, but now --

A. There is no sense in citing a cover page and so on.

Q. But you testified you believe these are minutes of a meeting, correct?

A. That's correct, yes, sir.

Q. And this first document is dated October 21, 1997, correct?

A. Yes, sir.

Q. Do you believe that there are additional pages of minutes from October 21, 1997?

A. No.

Q. Okay. Sir, the same question on -- for the document under tab 2. That's a document that you believe are minutes of a meeting from November 13, 1997, correct?

A. Yes.

Q. Do you believe that there are other pages of the minutes from that meeting?

A. I have no way of knowing that. These are all the minutes that I saw. I have no reason to believe that there are more minutes on this issue, and the reason I'm answering that this way is that there was room left under this -- there was room left on this page. So, I presume if there were more minutes to have related regarding that meeting, they would have written them on the rest of the page. That's all I saw.

Q. Sir, the document under tab 3, you believe that those are minutes of a meeting from January 15th, 1998, correct?

A. Yes, sir.

Q. You don't believe that there are any other pages missing from those minutes, do you?

A. I have no reason to believe that, sir.

Q. Now, sir, these are not the only documents of this format that you reviewed, correct?

A. That is correct, yes, sir.

Q. There were what you believed to be minutes from different meetings, correct?

A. Yes, documents analogous to this extended back -- I believe as far back as 1995 or maybe even earlier. They're all in the same format.

Q. Okay. Now, putting aside for a moment the format of these particular documents and analogous documents that you've seen --

A. Yes, sir.

Q. -- were there any other minutes of meetings dealing with Upsher-Smith's clinical studies that you reviewed?

A. I -- I just don't recall, sir.

Q. You don't cite any on page 31 of your report, correct?

A. I don't believe I do, no, sir.

MR. CURRAN: Your Honor, I have a few more binders I want to pass out.

JUDGE CHAPPELL: Okay.

BY MR. CURRAN:

Q. Dr. Levy, before I move on to any other documents, I do have a few more questions dealing with the binder you have in front of you, the three tabs.

A. Okay.

Q. I'd like to understand what it is in these documents that you relied upon in reaching your conclusions in this matter, okay?

A. Okay.

Q. So, let's begin with the document under tab 1.

A. Okay.

Q. And sir, that's the document dated October 21, 1997, correct?

A. Yes, sir.

Q. Sir, what is it in that document that forms the basis for some aspect of your opinion in this matter?

A. May I read it for a moment, sir?

Q. Of course.

A. (Document review.) Okay. So, what is it that led to my opinion?

Q. What is it about this document that creates the foundation for some opinion you're expressing in this matter?

A. I think there are two or perhaps three

significant elements on this particular page.

Q. Maybe we can -- well, I'm sorry, you go ahead. You tell me what the elements are.

A. Okay. I think the first is what they identify as issue number one -- well, actually, there's two issue number ones, but the first one, where it says, "Issue, critical path is currently dependent upon the PK study." I reviewed these documents, as I said, going back to '95 or perhaps even earlier, and during this entire period they were seeming to have difficulty getting this pharmacokinetic study done, which is -- and I should say that this is absolutely vital. It's vital to any new drug application. It's particularly vital to a so-called sustained release formulation, because the whole game of the sustained release formulation is pharmacokinetics, so --

Q. What else in this document --

A. Well, I'm trying to answer your question, sir, so --

Q. Okay, and I'm just asking, what in the document forms the basis for an opinion on that?

A. Well, first the fact that this PK problem or PK issue is -- has still not been resolved. It's now almost the end of October, and they had planned to file an NDA in December, and they didn't even have their PK

study off the ground yet, and that was going to be essential. So, that's -- that's one element that's leading to my -- the general formation of my opinion.

The second of these is this thing where -- a little bit -- about two-thirds of the way down the page where it says, "Action, alternate strategy for an ANDA approval has been identified. A project team has been initiated to prepare a project plan," presumably about the ANDA approach. Those are two, you know, pretty vital elements of fact here.

And then the third is that they -- they note on this page that Kos has received approval of Niaspan.

Q. Okay.

A. I would say in order of importance to me in terms of my thinking about this particular --

Q. Well, I'm not asking you anymore. I just want you to identify what facts --

A. Okay, those are three elements on this page.

Q. Okay, let's go to tab 2.

A. Okay.

Q. Sir, the document under tab 2, there's reference again to Kos receiving approval of Niaspan, correct?

A. Yes, sir.

Q. And there is further reference to the alternate

strategy for an ANDA, correct?

A. Yes, sir.

Q. Are those the two elements on this document that you relied upon in forming your opinion?

A. Well, no, there's a -- I mean, the -- you know, perhaps most significant, because this is now relating -- you know, in the previous document, they said they were formulating an ANDA strategy, but in this document, it gets to be a little bit more serious, because they say the NDA will -- I think they mean will continue -- with minimal activity while the ANDA strategy is formulated. So, what this is saying is they're basically back burnering the NDA strategy.

Q. Okay. So, you understood that to mean they were putting the NDA on the back burner, and you relied upon that understanding in forming your opinion in this matter, correct?

A. Yes, sir.

Q. Let's go to tab 3. Sir, in this document, what is it that you've relied upon in forming your opinion?

A. Where it says, "Project has been put on hold, only minimal activity will continue."

Q. What did you understand that to mean?

A. I think what it says, you know, they were putting the project on hold. They weren't doing any

further work on this project.

Q. And what did -- what did you understand that to mean in terms of their clinical study work?

A. It means a lot of things. You know, I mean, some of this is in black and white, you know, they were stopping everything they were doing, and so at the very least, they would not have completed the PK studies, the pharmacokinetic studies, that were mandated.

Frankly, in this -- this is trying to -- if you will read between the lines of this document in some sense --

Q. Is that what you did?

A. Sir, I'm formulating an opinion. I mean, one takes information and extrapolates that information as best one can. I mean, I wasn't there. I don't know what drove their decision-making. It was very surprising to me. I mean, "surprising" is an understatement, that they're putting this project on hold when they supposedly completed two pivotal trials.

The issue of Niaspan's having been approved certainly was no surprise to them. They knew the -- I mean, they knew what their competitor was doing. They had known for years that Kos was a couple of years ahead of them, and so it should have been no great surprise that a product -- that Niaspan was approved,

and they were going forward supposedly with their -- with their NDA project that fact notwithstanding.

Now they say, you know, Kos is approved. Well, so what? You know, they still should be going forward with the NDA. They stopped it. And so that -- that says -- you know, the question -- the obvious question is, well, why would they stop it? They've finished these two pivotal trials, and one -- one possibility is that they themselves questioned the -- the merits of what they had already done.

Q. So, on the basis of these documents that we've just reviewed, you concluded, reading between the lines and otherwise, that Upsher-Smith was stopping all work on its NDA, correct?

A. No, that's not my conclusion. That's their -- they're saying that. I'm not -- I didn't need any extrapolation to come to that point. What I'm trying to answer you, sir, is they stopped an NDA at supposedly -- not the 11th hour, but 11th hour, 59th minute --

Q. Yeah, but what is it that you believe they stopped?

A. They stopped the idea of registering this compound as a new drug in the United States of America after having supposedly completed two pivotal trials

and having nothing between them supposedly but a simple PK study to do.

Q. All right. So, it's your understanding and belief based on these documents that Upsher-Smith terminated its work on the PK study and on the clinical trials materials, correct?

A. That's what they said.

Q. Okay. And that's the basis -- and you base your opinion on that understanding, correct?

A. I'm not sure what you're asking me, sir.

Q. Okay, I'll withdraw that question.

Your Honor, I've got a bunch of binders to distribute. Would Your Honor want to take a break before I proceed with this? I wouldn't mind.

JUDGE CHAPPELL: It's about 11:10. Why don't we take our midmorning break. We will recess until 11:30.

MR. CURRAN: Thank you, Your Honor.

(A brief recess was taken.)

JUDGE CHAPPELL: Mr. Curran, do you have your exhibits together?

MR. CURRAN: Yes, and there's a lot of them, Your Honor, but we're going to handle them the best we can.

JUDGE CHAPPELL: All right, back on the record,

you may proceed.

Off the record for a second.

(Discussion off the record.)

JUDGE CHAPPELL: Mr. Curran, you may proceed.

THE WITNESS: Mr. Curran, do you want this back from me?

BY MR. CURRAN:

Q. No, if you wouldn't mind holding on to that, Dr. Levy, we are going to come back to that.

A. Okay.

MR. CURRAN: Your Honor, may I approach the witness to present the exhibits to him?

JUDGE CHAPPELL: Yes.

BY MR. CURRAN:

Q. Dr. Levy, this is SPX 1096. It's heavy.

Dr. Levy, do you have SPX 1096 in front of you?

A. Would you like me to look inside here, sir? I don't know what's in here.

Q. Well, do you have it in front of you?

A. If this is SPX -- yes, I do.

Q. I would like you to look at it, sir. I'd like you to take out the contents of the Redweld.

A. Okay, just -- well, the whole thing?

Q. I'd like you to flip through the whole thing.

A. Okay.

Q. I'm not going to ask you to read it at this point in time.

A. Is there anything in particular you're wanting me to look for or look at?

Q. Yeah, my question is, have you reviewed and analyzed these documents before, because none of them are identified in your report or other listings of information you relied upon?

A. Sir, at the risk of, you know, being inaccurate, I don't recall having seen anything in this first pile. Let me look in the second, if I may.

Sir, do you mind if I put these up here?

JUDGE CHAPPELL: You may.

THE WITNESS: And I'm just -- literally just flipping through the pages, sir, and I mean, I --

BY MR. CURRAN:

Q. Right.

A. So --

Q. And Dr. Levy, for the record, there are not specific piles. Any piles there are of your making. This is a single stack of documents.

A. Okay. (Further document review.) I mean, they all look to seem -- they all seem to be documents on the Clintrials letterhead, and -- unless I'm missing something, and I'm not really looking at what's in

them.

Q. Clintrials is a CRO, Dr. Levy, correct?

A. Yes, it is, sir.

Q. Dr. Levy, what I have done is because this is an unwieldy way to review documents, my colleagues and I have put these documents into binders for specific periods of time, and what I'd like to do, with the Court's permission, is to present you with a binder for one of the years covered by the documents in this SPX 1096.

A. Sir, to examine your -- I mean, just to give you, you know, a quick answer, if you will, I don't believe I have seen any of these documents. I don't recall seeing any of these documents, sir.

MR. CURRAN: Your Honor, may I circulate some binders at this point in time?

JUDGE CHAPPELL: For what purpose?

MR. CURRAN: For the purpose of showing the witness specific documents as part of my cross examination.

JUDGE CHAPPELL: Hypothetical, impeachment, what reason?

MR. CURRAN: All impeachment, Your Honor.

JUDGE CHAPPELL: You may. Have you provided copies to complaint counsel?

MR. CURRAN: Yes, doing so as we speak, Your Honor.

THE WITNESS: Mr. Curran, these documents that I have here is what you're handing out in the binders or am I getting another binder?

MR. CURRAN: I am going to be giving you those same materials in organized binders.

THE WITNESS: Okay.

MR. CURRAN: If you will leave those there, we'll gather them up.

May I approach, Your Honor?

JUDGE CHAPPELL: Yes.

THE WITNESS: Thank you.

JUDGE CHAPPELL: Thank you.

MR. CURRAN: You're welcome.

BY MR. CURRAN:

Q. Now, Dr. Levy, what I have done here is assembled, with the help of my colleague, assembled the documents from 1996 out of SPX 1096.

A. Okay.

Q. Now, sir, I'm not -- mercifully, I'm not going to be taking you through all of these documents, but I do want to pick a document just to explain what these are. If you look under, for instance, tab 2.

A. Okay. I see it.

Q. Sir, the first couple of pages under tab 2 -- and those, for the record, have a Bates number of Upsher-Smith-FTC-093265 and 093266. Do you see those?

A. Yes, sir.

Q. Sir, the first two pages appear to be an agenda of a conference call between Upsher-Smith Laboratories and Clintrials Research, Inc. --

A. Yes, sir.

Q. -- from on or about January 5, 1996?

A. Mine says January 12th, I believe, sir.

Q. Okay. Do you see a 5 and then a line through it and then a handwritten 12?

A. Yes, I do, sir.

Q. Okay. Sir, do you see the fax line on this document?

A. The fax line -- yes, I do, sir.

Q. Okay. And that indicates received January 5, 1996, correct?

A. I'm not sure if it was received or sent, but January 5th is up there, yes.

Q. Okay. Sir, that indicates that -- well, it's an agenda, right?

A. Yes, sir.

Q. And the categories on this agenda are monitoring issues and then data management issues and

then other issues, correct?

A. That's the headings, yes, sir.

Q. Okay, those are the headings. And then after those first two documents --

A. First two documents, sir?

Q. Right, after the first two documents, staying under tab 2 --

A. Okay.

Q. -- then there are minutes of a conference call, correct?

A. It appears so, yes, sir.

Q. And again, for the record, this document shows Upsher-Smith-FTC Bates number 093267 through 093270, correct?

A. Yes, I think so, sir. I'm not -- these numbers all confuse me, but I believe that's correct, sir.

Q. Okay. Now, sir, this appears to be minutes from a conference call held on January 12, 1996, correct?

A. Yes, sir.

Q. And it indicates that the attendees include a group of executives from USL. Is that right, sir?

A. Yes.

Q. And a group of executives or employees of CTR, correct?

A. Yes, sir.

Q. Do you have an understanding as to what CTR is?

A. I presume it's Clintrials.

Q. Sir, who are the people listed there from USL?

A. The -- I believe the only two names that I -- that I recall, I may have seen the other two names, but certainly Mark Halvorsen's name I have seen and Marge Garske's name, if I'm pronouncing them correctly, I've seen before. I don't -- I don't recall exactly what their titles are.

Q. Both of those names came up yesterday, correct?

A. I don't know if Ms. Garske's name came up yesterday or not. I've seen her name in various and sundry meetings.

Q. Now, yesterday you testified that you had not read a deposition of Mark Halvorsen, correct?

A. I believe that's correct, yes, sir.

Q. So, it appears that looking at the documents under tab 2 as a whole, we have two pages of an agenda of a meeting, and that was faxed on a particular date, and then we have after it minutes of the same meeting faxed on a subsequent date, correct?

A. Yes, sir.

Q. And you can see from the table of contents and from the contents of this binder, there were

approximately 33 telephone conferences and subsequent minutes prepared during 1996, correct?

A. You mean assuming that all these tabs are the same sort of thing?

Q. Yeah, and take a moment to get comfortable that that's the case.

A. Well, I mean, it will take more than a minute for me to go through it. I mean, I don't have any problem with -- you know, if you're going to represent that to me, I don't see any reason to disbelieve you on that. I mean, I'm happy to -- if it's important for the record for me to go through each of these, I'll do that, but I -- if you're representing it as such, I don't see any reason to doubt you.

Q. That's fine. You don't have any reason to doubt that these calls took place, correct?

A. No, sir.

Q. You don't know one way or the other, right?

A. Yes.

Q. I'd like now to jump to the binders with the 1997 conference calls and minutes.

If I may, Your Honor?

JUDGE CHAPPELL: You may.

MR. CURRAN: I'm providing a copy to Mr. Silber.

MR. SILBER: Thank you.

MR. CURRAN: May I approach?

JUDGE CHAPPELL: Yes.

BY MR. CURRAN:

Q. Dr. Levy, the documents in this binder appear to be more of the same for a different year, correct?

A. Well, the index page or the -- the first page seems to suggest that, and if you'd like I'll -- you know, whatever is your wish, I'll look at whatever you like.

Q. Sir, it appears that there were approximately 43 weekly telephone conferences and resulting minutes for these sessions between Upsher-Smith and Clintrials, correct?

A. That's probably -- well, I mean, I don't -- again, I don't mean to nit-pick this, but just looking at the front page of this document, which seems to be sort of a log of them, it appears that roughly a third of the calls were not made on these respective dates, and I don't know if they -- if there's a tab for where there was a no call. So, I just don't know that without looking through all these, but --

Q. There is not a tab where there was no call, and that's why there are 43 tabs instead of 52.

A. Okay, then that's a fair comment.

Q. Sir, I'd like to direct your attention to some of the documents within the tabs here, if we can start by jumping to tab 27.

A. Okay.

Q. Sir, the documents under this tab appear to relate to telephone conferences in July of 1997, correct? There's a fax cover sheet and then --

A. Yes, I believe so. That's correct, yes.

Q. -- and then there's an agenda, correct?

A. Is that on the second page? Yes.

Q. And the third page, correct?

A. Yes.

Q. And sir, do you see that the subjects being discussed, item one, 920115?

A. Where is that, sir?

Q. That's on the second page under the tab. It's the first page of the agenda.

A. 920115? Yes, I see that, sir.

Q. Does that number mean anything to you?

A. Yes, it does.

Q. What's that mean?

A. That was one of the two pivotal trials. That was the pivotal trial that I actually saw the summary write-up on.

Q. Sir, item two in this agenda, 900221, does that

number mean anything to you?

A. Yes, it does also, sir.

Q. What does that mean to you?

A. That was the second so-called pivotal trial that had -- the summary of which had not yet been completed and was not included in the dossier that Mr. Audibert reviewed. There was just a -- oh, a three or four-page summation of the information from that trial.

Q. And that's the other pivotal trial, correct?

A. Yes, sir.

Q. Okay. Item three, 920944, does that number mean anything to you?

A. Vaguely, I think -- and I'm -- at the risk of being inaccurate here, I think that 944 was the number of one of the other trials, information on which I didn't see other than the title.

Q. That's one of the follow-on clinical studies, correct?

A. One of the open-label follow-ons, yes, I believe that's correct. But I'm not sure of that, sir, but I believe that that's correct.

Q. Sir, item four on this agenda, which is over to the second page, the numbers there appear 920837, correct?

A. Yes, sir.

Q. Do those numbers mean anything to you?

A. No, I don't recall that number. That number doesn't mean anything to me.

Q. So, you don't know whether or not that's another follow-on study?

A. I just don't recall, sir. I don't -- I don't dispute it. I just don't remember that number.

Q. And based on what you see in this agenda, it appears that work was being done in connection with clinical study 920837, correct?

A. May I read that for a moment, sir?

Q. Sure.

A. (Document review.) It is seen -- I mean, to answer your question --

Q. Was the subject of discussion, correct?

A. It seems that -- I can't say whether work was being done, but it seems that something was being done about that, on that -- on that program.

Q. Now, sir, do you see -- first of all, there's handwriting all over this agenda, correct?

A. Yes, there is, sir.

Q. And do you see the handwriting toward the bottom of the second page?

A. I see -- yes. I'm not sure what you're referring to. There's a lot of handwriting on this

document.

Q. Do you see where it says in big letters, "Regulatory Needs Reports By September 15th"?

A. Oh, yes, sir.

Q. Okay. Sir, I'd like to direct your attention now to the documents under tab 29.

A. Okay.

Q. Sir, there you see minutes of a meeting from -- of a conference call on August 1st, 1997, correct?

A. I'm sorry, August 8th, 1997? Yes.

Q. August -- well, okay, the fax is August 8th, 1997, and it refers to a telephone conference call from a week earlier, right, August 1st, 1997?

A. Yes, you're right, sir. I stand corrected.

Q. And it indicates that there is a group of participants, approximately a dozen?

A. I don't see that on this first page. Do you want me to turn it over or --

Q. Yeah, please, take a look at the second page under the tab, the first page of the minutes.

A. Okay, yes, I see that, sir.

Q. Okay. There's approximately eight people from Clintrials, correct?

A. One, two, three, four -- yes, sir.

Q. And there's Mr. Halvorsen and Ms. Garske again,

correct?

A. Right.

Q. And there's reference to CSR and one Claude Drobnes attending?

A. Yes.

Q. Do you know who Claude Drobnes is?

A. No, I don't, sir.

Q. And then there's reference to NT, and there are two people whose names appear there, John Lorus and Beth Federman (phonetic).

A. Yes.

Q. Do you know what NT refers to?

A. No, I don't, sir.

Q. Do you know who John Lorus or Beth Federman are?

A. No, I don't.

Q. Sir, I'd like to direct your attention to the second page of the minutes.

A. Okay.

Q. Toward the bottom, after all the discussion of the clinical trials --

A. Okay.

Q. -- do you see Section 6, Other Issues?

A. Yes, sir.

Q. Okay. Do you see there where it says, "Major

issues are being made by USL regarding NDA submission"?

A. Yes, I do, sir.

Q. And it goes on to say, "Niacor competitor received approval this week, and this may affect NDA strategy"?

A. Yes, I see that.

Q. Okay. I'd like now to refer your attention to the subsequent tab, number 30.

A. Okay.

Q. And sir, in particular, I'd like you to look at the sixth and seventh pages under there --

A. Sixth and seventh pages?

Q. That's right, and there you'll see minutes of a conference call on August 8th, 1997.

A. I must have done this wrong, sir. I'm --

Q. Sure.

A. I went six pages forward, and I got a blank.

Q. Okay.

A. Can you help me -- what is the --

Q. Yeah, in my set, there is a fifth page which is a fax cover sheet to Mark Halvorsen from Clintrials Research. Do you have that in front of you?

A. Can you possibly give me this Upsher-Smith-FTC number? That seems to be --

Q. Of course. 093572.

A. I'm on it. Thank you, sir.

Q. Okay, and turn the page.

A. Okay.

Q. And there you have minutes of an August 8, 1997 conference call between Upsher-Smith Laboratories and Clintrials Research, Inc., correct?

A. I see that, sir.

Q. Okay. And there again, do you see discussion of analysis and medical writing for the various clinical trials, correct?

A. I just see the heading, sir. I haven't read it.

Q. Well, you see the first heading is 920115, correct?

A. Yes.

Q. We've already established that's one of the pivotal clinical studies, correct?

A. Yes, sir.

Q. And under that there's two subheadings, Analysis Update and Medical Writing Update, correct?

A. Yes.

Q. And then the next section deals with clinical study 900221, correct?

A. Yes.

Q. And the next major heading deals with clinical

study 920944, correct?

A. Yes.

Q. Over to the next page, there's reference to the clinical study 920837, and then below that there are some additional issues addressed, right?

A. Yes, it is.

Q. Okay. And under Roman VI, Other Issues, it says, "Competitor's approval will not affect the current plan for submission," correct?

A. Oh, at the bottom. Yes.

Q. Okay. I'd like to ask you to jump ahead to tab 38.

A. Okay.

Q. Are you at tab 38?

A. Yes, I am.

Q. Let's see if we can do this. The -- I'd like to refer your attention to the fourth page -- strike that -- the fifth page under that tab where the Bates number is Upsher-Smith-FTC-093521. Got it?

A. Yes.

Q. Okay, thank you. That appears to be minutes to a conference call on October 24th, 1997, correct?

A. Yes, it does, sir.

Q. And again, that's a telephone conference between Upsher-Smith Labs and Clintrials Research,

correct?

A. I presume so, yes.

Q. Okay, the usual suspects in attendance, correct?

A. Yes.

Q. Okay. A group from Clintrials, a group from USL, this Claude Drobnes person again, correct?

A. Yes.

Q. And John Lorus and Beth Federman again, correct?

A. Yes.

Q. Toward the bottom of that page, sir, do you see the discussion of the 920944 clinical study?

A. Yes.

Q. Do you see the subheading Analysis Update?

A. Yes, I do.

Q. Do you see the third -- the second of the three bullet points?

A. Yes, I do.

Q. Okay. Do you see where it indicates that daily conference calls have been scheduled with NT during their review of the draft tables?

A. Yes, I see that.

Q. Sir, I'd like to refer your attention to the document under tab 42.

A. Okay. Okay.

Q. There, sir, do you see documents relating to conference calls or a conference call on December 5, 1997?

A. Let's see, this thing says December 4th. My -- this cover sheet says December 4th. Am I looking -- okay, the next page says December 5th. The agenda page says December 5th.

Q. Very good. Sir, I'd like to refer your attention to the fifth document under that tab.

One moment, please.

A. Is that 93949? I'm sorry.

Q. Let me make sure we're on the same page, if you will. We're under tab 42, correct?

A. Yes, sir.

Q. Okay, I want to refer you specifically to the page that's Bates numbered Upsher-Smith-FTC-093503.

A. 3503?

Q. Yes. In fact, I believe it's the last page.

A. Oh, okay, yes. I'm sorry.

Q. Please forgive the confusion here.

A. I've got it, sir.

Q. Okay. And I want to refer your attention to the section two-thirds of the way down the page there. Do you see the item Roman VI where it says "NDA"?

A. Yes.

Q. Do you see the third bullet point or arrow there?

A. Yes, I do.

Q. Okay. Do you see where it says, "M. Halvorsen informed the team that although USL is not going forward with filing the NDA, there is a possibility that they will proceed in Europe"?

A. Yes.

MR. CURRAN: Your Honor, at this time I'd like to distribute documents dealing with 1998, providing a copy to Mr. Silber.

JUDGE CHAPPELL: You may, okay.

MR. CURRAN: And to Schering-Plough.

May I approach?

JUDGE CHAPPELL: Yes, I said okay.

MR. CURRAN: Thank you.

THE WITNESS: Can I trade you?

MR. CURRAN: Sure.

BY MR. CURRAN:

Q. Okay, Dr. Levy, please familiarize yourself with this binder. Again, more of the same, correct?

A. It seems to be, yes, sir.

Q. Okay. This time for 1998, correct?

A. Yes.

Q. I'd like to refer your attention to the document under tab 2 -- maybe I should say documents, but the pages under tab 2. Are you there?

A. I'm at page -- I am at tab 2, sir, yes.

Q. Okay. I'd like to refer your attention to a document third from the back there. It's a document that bears the Bates number Upsher-Smith-FTC-093836.

A. Okay.

Q. Sir, this appears to be yet another conference call between Upsher-Smith or minutes of a conference call between Upsher-Smith and Clintrials, this time dated January 9, 1998, correct?

A. Yes, sir.

Q. Okay. And it indicates representatives of Clintrials, Upsher-Smith, CSR and NT all participating, correct?

A. Yeah. I think the CTR group seems to have been progressively decreasing over this period. I think we started with about eight and now we're down to two of them, but yeah, the same group.

Q. Sir, I'd like to direct your attention to the second page under this -- of the -- or the second page after the start of the minutes there. This is the document Bates numbered Upsher-Smith-FTC-093837.

A. I'm there, sir.

Q. Toward the bottom of that page, do you see reference to Roman IV, ISS-115 and 221?

A. Yes.

Q. What does ISS stand for?

A. I don't know what its -- I mean, it probably is interim safety summary, but I don't know. I don't know what -- I don't know what they're using that acronym for.

Q. Sir, do you see the second bullet point that's out to the margin there under Analysis Update? To be more specific, where it says, "Draft tables, date to be determined, USL will be providing the ISS draft tables to their European partner. NT will QA the draft tables"?

A. Yes.

Q. Do you see over on the next page, there's reference to study prioritization?

A. Yes.

Q. And do you see the bullet point under that that says, "Studies were prioritized by USL in the following order"?

A. Yes.

Q. "221, 944, 837, ISS."

A. Right.

Q. "M. Halvorsen would like to complete the study

reports"?

A. Yes.

Q. Again, sir, the date on this conference call is January 9, 1998, correct?

A. Yes.

Q. Sir, I'd like to refer your attention to the document under tab 10.

A. Okay.

Q. Are you there?

A. Yes, I am.

Q. Sir, the first page under that tab, which has a Bates number Upsher-Smith-FTC-093785, is a fax cover sheet to Mark Halvorsen from Clintrials, correct?

A. Yes.

Q. And the next two pages after that are an agenda from a March 27, 1998 conference call between Upsher-Smith Labs and Clintrials Research, correct?

A. Yes.

Q. And we've got the usual clinical trial numbers there, correct?

A. Yes, sir.

Q. Those are items for discussion in this agenda, correct?

A. Yes, yes.

Q. And then on the second page of this agenda,

sir, do you see the handwriting where it says, "Notified CTR that European partner will not pursue submission"?

A. Yes.

Q. Sir, I want you to flip forward five pages.

A. Forward in the same tab, sir?

Q. Yeah, in the same tab. Really the last two pages under that tab --

A. Okay.

Q. -- sir, are the minutes from the meeting whose agenda we just looked at.

A. Oh, okay.

Q. Sir, you're familiar that agendas are ordinarily prepared before a meeting, right?

A. Yes.

Q. And minutes are ordinarily prepared after the meeting?

A. Yes.

Q. All right, reflecting what occurred in the meeting, correct?

A. Yes.

Q. And these are the minutes from the March 27, 1998 meeting, correct?

A. It seems so, yes.

Q. And on the second page of those minutes, do you

see the section with the Roman numeral IV?

A. Yes, I do.

Q. Do you see under there where it says, "Analysis Update"?

A. Yes.

Q. And do you see in the second bullet point there the following sentences: "M. Halvorsen informed us that this will be the final iteration for the tables. USL's European partner has decided not to proceed with the drug. CTR will provide documentation explaining the error with the safety intent to treat patients. M. Halvorsen confirmed that draft is acceptable on the tables."

A. Yes.

Q. Sir, I want to ask you to flip, please, to the documents under tab 11. Are you there?

A. Yes, I am, sir.

Q. Okay. Do you see the first page under that tab is a fax cover sheet to Mark Halvorsen from Clintrials Research?

A. Yes.

Q. And then after that page, there's an agenda of a telephone conference call, this is the weekly call for April 3rd, 1998, correct?

A. Yes.

Q. And it's the -- the agenda with some handwritten notations on it, correct?

A. Yes, sir.

Q. Okay. On the second page of the agenda, do you see the section on ISS?

A. Yes.

Q. That's got the Roman V by it, correct?

A. Yes.

Q. And do you see the handwriting there where it says, "Received package, no additional work will be conducted by anyone on this"?

A. I see that, yes.

Q. I'd like you to flip forward in this -- under this same tab to the last three pages of this tab.

A. Okay.

Q. These are minutes from the April 3rd, 1998 conference call, correct?

A. It seems so, yes.

Q. Okay. Sir, I'd like to direct your attention to the second page of those minutes. Do you see the reference there to the clinical study 920944? It's toward the top of the page.

A. Oh, yes, I'm sorry. I was looking at the bottom. Yes.

Q. Do you see under B, Analysis Update?

A. Yes, sir.

Q. Do you see where it says, "Per M. Halvorsen, the draft tables will be considered final"?

A. Yes.

Q. And do you see the bullet point under that?

A. Yes, I do.

Q. Do you see where it says, "M. Halvorsen asked that NT provide their review comments to USL. All comments will be considered for M. Halvorsen's review prior to scheduling a conference call to discuss identified issues and recommended changes. All addendum documenting identified problems and recommended changes will be drafted"?

A. I see that.

Q. And sir, I'd like to refer your attention to the documents under tab 12.

A. Okay.

Q. Those documents relate to a telephone conference on May 19th, 1998, correct?

A. Yes, they do.

Q. Sir, I'd like to refer your attention to the sixth page under that tab. It bears the Bates number Upsher-Smith-FTC-093774.

A. I'm getting confused, sir. 774? Oh, I see, they're going backwards here. Okay, I'm there, sir.

Q. Okay. Sir, do you see the reference, for instance, to clinical study 920115?

A. Yes, I do.

Q. Do you see under the section Records Management Update?

A. Yes.

Q. Do you see where it indicates that boxes are being shipped to USL storage warehouse?

A. That first bullet?

Q. Yes.

A. Yes.

Q. Do you see also under Roman II, for study 900221, C, Record Management Update?

A. Yes, I do.

Q. Again, under there a reference to boxes being shipped to USL storage warehouse?

A. Yes.

Q. Over to the next page, to Roman III regarding clinical study 920944, under Records Management Update?

A. Yes.

Q. Again reference to boxes being shipped to USL for storage warehouse?

A. Yes.

Q. And likewise, under Roman IV, clinical study 920837?

A. Yes.

Q. And there again, under Records Management Update, reference to boxes being shipped to USL storage warehouse?

A. Yes.

Q. Sir, all of these documents that we've looked at from SPX 1096, from 1996, 1997 and 1998, you have no recollection of ever seeing those before, correct?

A. I'm -- pardon me, I'm confused. Do you mean -- I'm sorry. Do you mean these documents up here?

Q. Those documents up there as well as the ones in your lap in the binders we've been looking at.

A. I've not seen anything in the binders, and with the caveat it was a fairly cursory glance, I don't believe I've seen anything in this pile (indicating).

Q. All right. And when you were listing the documents you relied upon in your report and so forth, you tried to be complete and accurate in listing the documents you referred to and relied upon, correct?

A. Yes, sir.

Q. Sir, I'd like to ask you to go back to the binder we were looking at before the break, and that's the one --

A. This one?

Q. -- on the cover, yes, that says Niacor-SR

Product Updates.

A. Yes.

Q. Do you have that in front of you?

A. Yes, I do, sir.

Q. Sir, I want to go back to the document under tab 3.

JUDGE CHAPPELL: Hold on, Mr. Curran. You need to allow complaint counsel to find his place.

MR. CURRAN: Of course.

MR. SILBER: Thank you, Your Honor.

JUDGE CHAPPELL: I just noticed he's moving a number of binders there. I can see him for the first time in a half hour.

MR. SILBER: I'm getting buried a bit, Your Honor.

I'm ready now, thank you.

BY MR. CURRAN:

Q. Sir, do you have the document from under tab 3?

A. Yes, I do, sir.

Q. Sir, when we were discussing this document before, you referred to the statement that the product -- the project has been put on hold and only minimal activity will continue, correct?

A. That's what it says.

Q. Okay. Then right below that, in a part you

didn't refer to and you didn't quote in your expert report, it goes on to state, "All study reports must be submitted to the FDA. Action: Clinical will continue to work with Clintrials to complete reports. This represents a significant amount of resource hours."

Have I read that correctly?

A. Yes, you have, sir.

Q. Okay. And then under that, there's reference to analytical method development, correct?

A. Yes, sir.

Q. That refers to the PK study that you referred to earlier, correct?

A. No, I can't -- I can't conclude that from what's written here.

Q. You can't read between the lines and make that conclusion?

A. Sir, there are multiple analytical method development --

Q. Yeah, but --

A. -- requirements in the course of developing an NDA. I have no -- I don't -- there's no way of my knowing that this is for the PK study specifically.

Q. Okay, but your understanding is that the PK study was abandoned as well, correct?

A. There was no further reference to the PK study

from I believe it was September or October forward in any of these documents, and they abandoned the project, and so I didn't have to conclude either way. There was no further reference to it.

Q. So, you saw documents indicating that the NDA project was put on hold, so you assumed that the clinical studies and the PK studies were terminated as well, correct? Correct?

A. No, I'm -- I'm not trying to -- I'm trying to -- the project was terminated. The clinical trials were supposedly completed, and so it was not a question of whether or not the clinical trials were ongoing. I mean, if one believes all of the documents that I saw, the clinical trials had been completed. What seemed to have been stopped was the whole issue of evaluating these clinical trials and of putting these clinical trials -- not just, you know, sticking all the data in storage, but the processing of a new drug application, which is a -- you know, a major undertaking, and I -- and that's what would have had to have been stopped here.

They -- they couldn't stop -- they didn't have to stop what they had already done. They had completed the clinical trials supposedly. And so what they stopped was any further use of those clinical trials is

what -- I mean, they stopped the project.

MR. CURRAN: Your Honor, may I approach the witness to show him another document?

JUDGE CHAPPELL: Yes.

MR. CURRAN: And I promise I'll pick all of these up when we're done. These are SPX 333.

THE WITNESS: Okay.

BY MR. CURRAN:

Q. Dr. Levy, this is a November 1998 PK study prepared by MDS Harris, correct?

A. I'm sorry. I'm just reading the front page of it. I have no idea what it is, sir.

Q. You don't recall seeing this document before?

A. I've never seen this document before.

Q. Sir, going back to your Niacor-SR product update binder, tab 3?

A. Oh, this one?

Q. Yes.

A. Okay.

Q. Thank you.

A. Okay.

Q. Do you see toward the bottom of that page there's reference to MDS Harris completing the work on the method validation, correct?

A. Yes.

Q. And that's from January of '98?

A. Yes, sir.

Q. And that's on the same document where you were relying on the statement that the project has been put on hold, correct?

A. Yes, sir.

Q. In fact, MDS Harris completed the work on the analytical method development, correct?

A. I have no way of knowing that, sir.

Q. Okay. Sir, were the clinical studies completed?

A. I have no way of knowing that. I mean, I only have summary information on one and less than that on another --

Q. Okay, but you --

A. -- done by a CRO. I have no idea what was done. I only can say what was represented as having been done by Upsher-Smith in a very brief dossier that was reviewed by Mr. Audibert.

Q. So, when you reached your conclusions in this matter, you didn't know one way or the other as to whether the clinical studies that Upsher-Smith was doing were completed or not?

A. Sir, I had no reason to disbelieve anything that Upsher-Smith put in its dossier, and so I assumed

that those studies, particularly those two pivotal trials, had been completed. I -- nothing in my opinion or nothing in my -- any wildest conclusions at all assumed that there was any -- anything other than truthfulness in those -- in that dossier. So -- so, I presumed that they were finished.

You're asking me whether I know it. That requires a little bit more than just that belief. I can't know it unless I've seen the data.

Q. Dr. Levy, do you remember the conclusions that you expressed on your direct examination?

A. Yes, I do.

Q. Do you remember the third one, "Post-deal, neither party showed any serious interest in developing and marketing the drug"?

A. Yes, I do.

Q. Now, sir, when you were reviewing your conclusions at the end of your direct examination, you stated that any one of the three subparts to your conclusion was a sufficient basis upon which to conclude that the $60 million was not for Niacor-SR, correct?

A. Yes, sir.

Q. Do you stand by that conclusion?

A. Yes, I do.

Q. So, does that mean that if the $60 million payment was perfectly in line with value and precedent and everything else and that post-deal, the parties showed serious interest in developing and marketing the drug, that you would nonetheless conclude that the $60 million was not for Niacor-SR if the due diligence was strikingly superficial?

A. Yes.

Q. And does that mean that even if the $60 million was perfectly in line with the fair value and precedent and the due diligence was adequate or even thorough, that you would conclude the $60 million was not for Niacor-SR simply on the basis of post-deal conduct?

A. Yes.

Q. Does that also mean that if the due diligence was adequate or even thorough and post-deal, the parties showed serious interest in developing and marketing the drug, you would nonetheless conclude that the $60 million was not for Niacor-SR?

A. Your -- and the -- you're eliminating the first point?

Q. Yeah.

A. Yes.

MR. CURRAN: Your Honor, I have no further questions.

JUDGE CHAPPELL: Thank you, Mr. Curran.

Does the Government have any redirect?

MR. SILBER: Your Honor, we do have redirect. As has become somewhat customary, I think we would like to have an opportunity for me to consult with my colleagues about redirect. I was wondering if it may be an appropriate time to take a lunch break, since I would like to request at least 10 or 15 minutes to consult with my colleagues. I would anticipate the redirect being somewhere in the area of 30 to 45 minutes.

JUDGE CHAPPELL: Why don't you take a few minutes and consult, give me a better estimate of how much redirect you have, and then I'll decide whether we're going to take a break.

MR. SILBER: Certainly, Your Honor.

(Pause in the proceedings.)

JUDGE CHAPPELL: Okay, we're back on the record.

MR. SILBER: Your Honor, having briefly consulted with my colleagues, I think there may be some documents we may like to go through on redirect, so my guess is it will take about between half an hour to an hour to do the redirect.

JUDGE CHAPPELL: Okay. Since it is about

12:22, let's go ahead and take our lunch break. Let's recess until 1:20.

MR. SILBER: Thank you, Your Honor.

(Whereupon, at 12:22 p.m., a lunch recess was taken.)

AFTERNOON SESSION

(1:20 p.m.)

JUDGE CHAPPELL: You may proceed.

MR. SILBER: Thank you, Your Honor.

REDIRECT EXAMINATION

BY MR. SILBER:

Q. Good afternoon, Dr. Levy.

A. Good afternoon.

Q. I wanted to go back through some of the testimony on your review of clinical data relating to Niacor. If you recall, Ms. Shores asked you a series of questions about liver toxicity and the upper limits of normal. Do you recall that testimony?

A. Yes, I do.

Q. Okay. If we could start by you just telling us why liver toxicity is a concern for niacin drugs.

A. All the previous -- that is, prior to Niaspan, all the previous attempts to make a sustained release niacin preparation resulted in liver toxicity, and in several cases, not just an elevation of liver enzymes, which is sort of a screening test for this problem, but actually a fulminant hepatitis, that is, actually a destructive lesion of the liver that was -- you know, had serious pathologic conditions or consequences. So, with that sensitivity, certainly any entry into this

class would need to have focus on whether or not it had liver toxicity.

Q. Okay. And I believe in your cross examination, the term "upper limit of normal" was used. Do you recall that?

A. Yes, I do.

Q. Can you tell us what that term means?

A. Yes. Any blood test that, you know, we've all had has a range of what we refer to as normal. It's -- there's rarely, if ever, a single number that is said to be normal. It will range from X to Y. And the upper limit of that range is referred to as the upper limit of normal, and anything above the upper limit of normal is not normal, is abnormal.

Q. Okay. In completing your expert report, did you review clinical data regarding Niacor-SR?

A. Yes, I did.

Q. Okay. Paula, if you could pull up Dr. Levy's report and go to page 8, please. I think it may be the prior page. It's the table that I'm looking for, the table of clinical data. That's it. And if you could just pull up for us the table at the top. Thank you.

Dr. Levy, is this where you analyzed clinical data regarding liver toxicity?

A. Yes, it is.

Q. And did you analyze it in the second and third lines from the bottom?

A. The second and third lines from the bottom and also significantly I believe the third line down from the top.

Q. Okay. In using this data, what measurement relative to the upper limit of normal did you use?

A. 1.5 times the upper limit of normal.

Q. Why did you use that level?

A. The use of a test like SGOT, SGPT, the so-called liver enzymes, these tests that, as I say, all of us have had in all of our physical examinations when they do a blood chemistry, are screening tests. That's all they are. They don't -- and what they signify is whether there is a suspicion or not of there being a problem.

And so that, for instance, you know, if you were to go to your physician, just putting it in real, you know, the simple terms that we can all relate to personally, if one were to go to his physician and have an SGOT and/or SGPT level that was above the upper limit of normal, and certainly one and a half times the upper limit of normal, it would elicit concern in this physician, and he would -- probably the first thing and the simplest thing he would do would be simply to

repeat it, because there are myriad things that can cause a test to be abnormal and not really signify any difficulty.

But it would be an absolute signal to him to look further, and -- and that's really the -- I mean, I was -- as I testified earlier, I was trying to put myself in Mr. Audibert's position. Here, he has a drug class that is known, absolutely known, to have problems with severe, significant liver toxicity. He has a significant population of patients in the clinical trial who first of all had elevated, abnormal, above the upper limit of normal liver function studies, and this third line, 30 percent or more of those patients dropped out of the trial, which is a very significant parameter, because of safety issues, most of which were -- if not all of which -- were these elevated liver levels -- liver enzyme levels.

So, all that said to me -- and I'm sorry to be so long-winded, and I'm trying to give you the answer -- is that it says simply that, you know, beware, look, investigate further. This is an abnormal screening test, and you better be careful.

Q. Are you aware of the measurement relative to the upper limits of normal that the FDA uses in its review of cholesterol-lowering drugs?

A. Well, it depends on what it's -- it depends on the type of use to which it's putting it. The FDA would use a screening test like this much in the same way that I would use it in terms of signifying to it that it should look further. The number that's been bandied about in here in some testimony about the three times the upper limit of normal. When something is three times the upper limit of normal, that means something bad is going on.

You know, you can, for instance -- if any of us were to exercise heavily, use our muscles heavily, shovel the snow, something like that, it's not unlikely that our SGOT, SGPT might go up a little bit. There are a number of things that can do that, to elevate it at a minor level, but those sort of things don't take it three times the upper limit of normal.

So, when the FDA -- the FDA realizes that people shovel snow, and they don't want a patient to be inordinately taken off a drug because they shoveled snow and the doctor happened to do the physical examination at that point, and so they have been conservative in setting the upper limit of normal as an index of liver damage at three times the upper limit of normal. That's not how I'm using it, and that's not how anybody reviewing a new drug or potential new drug

would view it.

Q. Now, Ms. Shores also -- she pulled out the PDR, that big, thick book --

A. Yes.

Q. -- and she walked you through some figures for liver toxicity for other cholesterol-lowering drugs. Do you recall that?

A. Yes, I do.

Q. And do you recall that some of those figures ranged from less than 1 percent up to about 5 percent?

A. Yes, I do.

Q. Does the fact that those drugs, these other cholesterol-lowering drugs, may have had liver toxicity levels of less than 1 percent to up to 5 percent change your opinion on whether there was a potential liver toxicity problem with Niacor-SR?

A. Not at all.

Q. Can you explain why?

A. Well, first of all, as I said a moment ago, the type of potential liver toxicity that had been seen with niacin compounds was not just a trivial elevation of a blood enzyme, but it was indeed the Real McCoy. It was destructive liver disease. The statins had been shown through use in millions of patients to have an exceedingly low incidence of those kind of, you know,

serious problems, and so an elevation of a screening procedure would, as the PDR suggests, you know, an elevation of the liver enzymes above a certain level would have said to the doctor, you better look further. It doesn't say that the patient's going to die of liver disease, but it says, you know, be careful, look further, and it's just prudent advice.

Q. I'm going to show you a document that Ms. Shores used with you in your cross. It is SPX 267, and I'll put it up on the ELMO. Let me focus in on the date.

Do you recall Ms. Shores showing you this document?

A. Yes, I do.

Q. And this document is dated June 29, 1993?

A. Yes.

Q. And I believe you testified that this was a telephone communication record that Upsher maintained on communications with the FDA. Is that correct?

A. Yes.

Q. Is this the type of document -- let me back up a step.

In your direct testimony, you explained to us a licensing evaluation process. Do you recall that?

A. Yes, I do.

Q. And one of the steps in there was regulatory review. Do you recall that?

A. Yes.

Q. Is this the type of document that would normally be looked at in regulatory review?

A. Yes.

Q. And why is that?

A. Just to get an indication of what the actual regulatory authorities have been saying, feeling about this project as one works his way through -- as the project is worked its way through the regulatory process.

Q. Do you know whether Mr. Audibert looked at this document?

A. I don't believe so.

Q. Did Mr. Audibert look at any documents on correspondence with the FDA?

A. Not that I know of.

Q. Do you know whether Mr. Audibert did any review of regulatory status at all?

A. Not that I'm aware of.

Q. Okay. Now, have you seen later correspondence or meeting minutes between Upsher-Smith and the FDA?

A. Yes, I have.

Q. Paula, if you could pull up CX 1382. Okay, and

if we could go back to the page bearing Bates number Upsher-Smith-FTC-107433, which is one, two -- it's the eighth page of that document.

A. Mr. Silber, would you mind if I had a hard copy of that?

Q. Yeah, I'm getting you one.

A. Okay, thank you.

MR. SILBER: Your Honor, may I approach?

JUDGE CHAPPELL: Yes.

BY MR. SILBER:

Q. Okay, Paula, if you could just pull up the caption at the top, the top three lines up there.

Okay, Dr. Levy, have you seen this document before?

A. Yes, I have.

Q. Can you tell us what it is?

A. They are minutes of a meeting that officials from Upsher-Smith had with the Food and Drug Administration in February of '97.

Q. So, this is approximately four months before Schering evaluated Niacor-SR?

A. Yes, it is.

Q. Okay. And Ms. Shores didn't show you this document during your cross examination, did she?

A. I don't recall.

Q. Okay, if we could pull up the last paragraph on this page.

And Dr. Levy, have you looked at this paragraph before?

A. Yes, I have.

Q. And can you tell us the significance of what's being expressed here?

A. In summary, there had been an ongoing dialogue with the FDA about what sort of pharmacokinetic studies would be required for this -- you know, for Niacor-SR, and this is just referring to some of those meetings and continuing that discussion.

Q. Okay.

A. It's identifying this -- I think it's really identifying the subject of this particular meeting which dealt with the very narrow issue of the pharmacokinetic studies that Upsher had not performed.

Q. Okay. Are you generally familiar with the issues concerning Upsher's development of this pharmacokinetic study?

A. I can't say I'm familiar with all the issues. This issue I seem to have more information on than -- than most of the others.

Q. Okay. What was the FDA telling Upsher about its pharmacokinetic studies?

A. I'm trying to find the words to say this delicately, because it's -- it was -- this was a strange communication to me. The FDA seems to have been telling Upsher for some time, including in this document, what sort of pharmacokinetic studies they had to do, and Upsher seemed not quite to -- not to quite get it, you know, they -- they -- the FDA was telling Upsher-Smith what it had to do to at least fulfill this narrow requirement, and remember, this is only one of a multitude of requirements that an NDA has, but at least on this one, the FDA seemed to be being unduly clear, and the back and forth seemed to be that Upsher seemed to be trying to negotiate this issue with the FDA as to just what they had to do or not have to do.

Q. Okay, let's turn to the next page of this document, which is Upsher-Smith-FTC-107434, and if we could pull up the second paragraph.

Dr. Levy, the last line of this paragraph says, "Mr. Hunt supported Dr. Fossler's explanation, indicating that Upsher-Smith does not have adequate data to meet the regulatory requirements for an extended-release product."

What is the significance of that statement?

A. I think it sort of speaks for itself. I think the FDA was saying to them that, you know, this is a

sustained release product, and the whole game of a sustained release product is a pharmacokinetic parameter. I mean, you know, it means that the drug is being released slowly and absorbed slowly into the bloodstream, and that's the sort of thing that one derives from pharmacokinetic studies.

You know, for instance, Niaspan had done 14 pharmacokinetic studies, and here, the FDA is saying, you know, do it or it's not going to be approvable.

Q. Okay, let's pull up the fifth paragraph on this page.

Here it's saying Dr. Robbins stated that another significant concern is that Upsher-Smith has been unable to validate the analytical methods necessary to measure the analytes in plasma. How is this concern significant?

A. Well, in its simplest sense, it's significant in that this is a -- before you can do a pharmacokinetic study, what you're doing with a pharmacokinetic study is measuring the various components. I mean, niacin, sometimes the metabolites of niacin in the various body fluids after you administer the drug, so you would be measuring it in urine, be measuring it in blood, you may be measuring it in spinal fluid, and -- depending on the nature of

the drug.

And in order to measure it, you have to have what biochemists refer to as an assay; that is, a test, a quantitative test that enables you to take the body fluid and determine there's X amount of niacin or whatever it is you're trying to measure in it. And that's sort of step one in doing a pharmacokinetic study, and they don't seem to have gotten past that step one.

Q. So, in this document, there's several concerns being expressed relative to the process for approval for Niacor-SR.

A. Yes.

Q. And the date on this document is February 5, 1997, correct?

A. Yes, it is.

Q. So, that precedes the evaluation that Schering did of Niacor-SR?

A. Yes, it does.

Q. Did Mr. Audibert have this document when he evaluated Niacor?

A. Not to my knowledge.

Q. And if you had this document -- putting yourself in Mr. Audibert's shoes, if you had asked for this document and seen this document, would this have

created concerns about licensing Niacor-SR?

A. Yes.

Q. And why would it have created concerns?

A. I think from two points of view. I mean, on the simplest sense, it would have said to me, we better do the pharmacokinetic study, because we're not going to be filing this NDA very soon unless we -- unless we do it, but more than that, it probably would have called into question everything else they did in their clinical program, because if they can't pull off a PK study, Lord knows whether they can pull off a clinical study.

Q. Okay. I believe that Ms. Shores asked you some questions and showed you some documents concerning the period of time when Schering was looking at Niaspan in early 1997.

A. Yes.

Q. Do you recall that?

A. Yes, I do.

Q. Does the fact that Schering looked at Niaspan in early '97 before looking at Niacor, does the fact that they did that review eliminate the need to do due diligence on Niacor?

A. Not one bit.

Q. Could you explain that?

A. Yes. I think that looking at a drug like -- like Niaspan would have given them some information, assuming that these are comparable or similar drugs, would have given them some indication on the size of the market and, you know, the interest, the potential interest in this drug, but in terms of the drug itself, anybody in the industry knows through -- usually through painful personal experiences that very, very closely related drugs unfortunately don't behave similarly.

I mean, I've actually already testified that counsel during my deposition pointed out to me that when I was at Abbott, the drug was discovered called Omniflox or temifloxacin, and this is a class of drug related to the now very famous Cipro or ciprofloxacin. It's a structural absolute first cousin of this drug. It looked -- it looked great, but unlike Cipro, Omniflox or temifloxacin had to be withdrawn from the market very shortly after it was introduced because of toxicity. So, here's an example where two very closely related drugs certainly didn't behave similarly.

Right in the backyard of this subject matter, I've asked -- I've been asked to testify about the statins. The statins are generally accepted throughout the medical community as very good and quite safe

drugs. Just a short while ago, Bayer, a major company, had to withdraw its statin, Baycol, because it killed people, and I don't think that too many of us would like to have thought that we would want to repeat that.

Now, in this particular matter, right close to home, is the fact that, yes, Niaspan looked pretty good, and had they reviewed Niaspan and then Niacor came along, okay, but remember, there were a lot of compounds, also sustained release niacin preparations, that antedated niacin or Niaspan, and they killed people. And so it would -- you know, are you going to believe that your drug is like Niaspan, or are you going to believe it's like all the other sustained release niacins that antedated Niaspan?

The bottom line is nobody, nobody in this industry would review a drug and then accept without review another drug even if it was a close first cousin of that drug without repeating the scientific due diligence.

Q. Okay, Paula, if you could pull up the demonstrative with the noncontingent payments. Just for identification again, this is CX 1604.

Dr. Levy, do you recall that Ms. Shores walked you through some of these deals during your cross examination?

A. Yes, sir.

Q. Okay. And she had asked you some questions as to whether you were familiar with the expenditures Schering made or would need to make to develop these drugs.

A. Yes, sir.

Q. And on this chart, you didn't include any such expenditures. Is that right?

A. Yes, sir.

Q. Why is that?

A. What a company spends on R&D to develop in-licensed product is one of its operating expenses. I mean, I didn't put human resources on here, I didn't put their marketing department on here. It's -- it's totally unrelated. We're talking here to what they paid for a license deal. We're not talking about the operating expenses of Schering-Plough.

I mean, drug companies have as their business to develop drugs, and so one presumes that they had a budget to do that. It's -- it's no more relevant to this slide than their human resources budget.

Q. Does the fact that Schering may have paid tens of millions of dollars in research expenditures alter your opinion at all as to whether the $60 million payment was for Niacor?

A. Not one iota.

Q. And why is that?

A. Drugs are expensive to develop. It's a legitimate and expected expense, and I think that Schering makes those expenses, as does -- or incurs those expenses, as does any pharmaceutical company. That has nothing to do with the fact that they made a very large license fee for one such drug.

Q. I think after Ms. Shores went through this with you, she talked about some other industry deals concerning up-front payments and other types of payments. Do you recall that?

A. Yes, I do.

Q. Do you recall whether any of those deals concerned cholesterol-lowering drugs?

A. No, I don't think so.

Q. Are you familiar with any deals for cholesterol-lowering drugs that are germane to your opinion regarding the $60 million payment?

A. Yeah, there's one that was, you know, interesting in its omission, and it happened in March of 1996 where the second biggest drug in the world, Lipicor -- Lipitor I mean, atorvastatin, a statin, the world's biggest selling statin, was licensed in a very late stage, I believe it was -- you know, I don't know

if it had been filed, but it was very late stage III, from Warner Lambert to Pfizer, and the license fee, the up-front, if you will, noncontingent cash payment was for the second biggest drug in the world $20 million, and milestone payments were in excess of $200 million, each of those milestone payments contingent upon approval in various jurisdictions.

Q. How did those payments compare to the payments Schering made for Niacor?

A. Well, the noncontingent cash payment was about one-third.

Q. Mr. Curran earlier today asked you about a valuation methodology called net present value. Do you recall that?

A. Yes, I do.

Q. And what is your opinion on the usefulness of net present value methodology for valuing pharmaceutical products?

A. I think net present value has utility for certain types of endeavor that we go through in the pharmaceutical industry. Net present value I think -- I know I've used and many of us have used to, for instance, evaluate the wisdom or lack of wisdom in, say, building a plant. I mean, net present value is comprised of two variables built into a formula. One

is an accumulation of cash flows over a given period -- accumulation of net present values over a period of, say, five years or sometimes ten years, and then there's another element of the equation that's referred to as the discount rate.

Where net present value, you know, is very useful is, for instance, if you're deciding to build a plant and you're now out-sourcing the manufacturing of this product, pharmaceutical product or other, and you're paying X amount for it, you will know what the change in cash flow, what the incremental cash flow advantage will be to your building this plant. You'll also know the cost of this plant. These will be known parameters that you're going to be able to pretty much predict over the course of the utility of this plant.

You also know what your cost of capital is, and so the discount rate is not -- is not guesswork. You know what your cost of capital is. And so you do an NPV to see whether or not this is a worthwhile use of that capital as opposed to alternative uses of that capital that you may have. You know, should you build a diagnostic plant or build a pharmaceutical plant? Those are the sort of decisions that are made all the time, you know, in big companies.

Now, when one contrasts that to the way it was

used here, it's very, very different, because --

Q. You say the "way it was used here," you're talking about --

A. The way it was used here in terms of trying to value Niacor-SR or any type of pharmaceutical product. There, these two variables are -- are just unknowns. I mean, I use the term, and I don't mean to be flippant here, but there's a very common term in the information technology world that we call GIGO, you know, capital G, capital I, capital G, capital O. That means garbage in, garbage out, and if you don't know -- if you're sort of guessing as to what the cash flows are going to be, and then if you don't have a clue as to what the risk factor is, hence what the discount rate should be, it's GIGO. So, you can do all the calculations you want, but it's still GIGO, and nobody is going to rely on it.

Q. Are you familiar with the positions other experts have taken in this litigation regarding net present value as it relates to Niacor?

A. Yes, I am.

Q. And can you tell us what you're familiar with?

A. Well, I think it makes the point. I mean, I've read several of their experts' depositions. I've -- as well as exhibits and assorted other documents, and what

one sees is across -- for the same product or products, across several experts and several depositions, the cash flow estimates have ranged all over the place, and the discount rate -- remember, the discount rate drives this. Whatever your cash flows are, even if the cash flows are fixed, you can get a heck of a big difference in the NPV if you choose a 10 percent discount rate than if you choose a 30 percent discount rate. I mean, it's huge.

So, if I remember correctly -- and I'm not sure I'm totally accurate in this, but I know their discount rates are all over the board, and I think they range from a low of about 13 percent up to about 30 percent, which, again, illustrates the point. It's GIGO. And indeed, one of their experts, I was pleased to see, amazingly, agreed with me totally. That was Mr. McVey, who --

MS. SHORES: Objection, Your Honor. Your Honor, objection. This is the expert that we dropped with the understanding that complaint counsel was not going to be using any of Mr. McVey's deposition testimony.

MR. SILBER: Your Honor, we agreed to not admit his testimony as substantive evidence. We are not seeking to admit his testimony as evidence. In cross

examination, Mr. Curran raised the question as to whether Dr. Levy performed valuation by net present value, and here I'm seeking to respond to that by showing how net present value has been used, and one way to do that is to show how other experts in the industry use net present value.

Now, Mr. McVey in his testimony stated an opinion very similar to Mr. -- to Dr. Levy's that he did not use it in his experience in the pharmaceutical industry, and he explained why, for reasons very similar to what Dr. Levy has stated, and I am simply trying -- Dr. Levy raised this point about Mr. McVey simply to illustrate the point that his opinion is consistent with others in the industry.

MS. SHORES: Your Honor, we agreed -- they complained about the number of our experts in this matter. We agreed to limit the experts on this issue with the understanding that they weren't going to be using any portions of Mr. McVey's deposition. If they want to renege on that deal and allow us to call Mr. McVey to explain what he said in his deposition, then we can revisit that.

JUDGE CHAPPELL: Mr. Silber, if you agree not to use McVey in any way, you're now doing so. The objection is sustained. Move along.

MR. SILBER: Okay, thank you, Your Honor.

BY MR. SILBER:

Q. Dr. Levy, do you recall Ms. Shores walked you through some communications after the deal was concluded between Schering and Upsher?

A. Yes, I do, sir.

Q. Okay. I'd like to go back through a few of those with you.

A. Okay.

Q. I'd like to give you the package of information that Ms. Shores had provided you labeled Post-License Conduct.

May I approach, Your Honor?

JUDGE CHAPPELL: Yes.

THE WITNESS: Thank you.

JUDGE CHAPPELL: Just so we're clear on the record, did you say that Mr. Curran used Mr. McVey's testimony when he was cross examining this witness?

MR. SILBER: No, that is not what I said, Your Honor. I said that he raised issues concerning why Dr. Levy did not use this net present value valuation methodology. I don't believe he spoke to Mr. McVey specifically.

JUDGE CHAPPELL: Okay, then in sustaining the objection, I'm telling you you can't use McVey. It

doesn't mean you can't conduct redirect on that issue.

MR. SILBER: Okay, that's fine, Your Honor. I think -- I think Dr. Levy explained his opinion in full. Thank you, though.

THE WITNESS: Your Honor, I apologize. I didn't -- I don't -- I don't know what's excluded and what isn't excluded, and I --

JUDGE CHAPPELL: We're learning, sir.

THE WITNESS: Okay, thank you.

BY MR. SILBER:

Q. Okay, Paula, if we could pull up CX 366.

Dr. Levy, if you could turn to CX 366, I believe it's the first document in this binder.

A. All right.

Q. Dr. Levy, what is the date on this document?

A. April 21st -- I'm sorry, August 21st, '97.

Q. So, this is after Mr. Audibert concluded his evaluation of Niacor-SR?

A. Yes.

Q. In fact, just about two months afterwards?

A. Yes, sir.

Q. Okay. And in the text of this letter, the first line, Mr. Audibert writes, "Thanks for sending me the protocols."

Do you see that?

A. Yes, I do.

Q. Okay. Tell us again what protocols are.

A. Those are the documents that spell out in detail how the clinical trial will be conducted.

Q. Is this something you generally look at in doing due diligence for an unapproved pharmaceutical product?

A. Yes, sir.

Q. And why is it that you would look at such documents?

A. Because you're going to be looking at the clinical results, and you're going to have to know in detail what the trial actually was. Otherwise, it's awfully difficult to interpret the meaning of any of the -- some of the data.

Q. Okay. And here, Mr. Audibert is thanking Ms. Garske for sending him these protocols two months after he completed his evaluation. Is that correct?

A. Yes, sir.

Q. So, from this it doesn't appear as though Mr. Audibert had this information at the time of his evaluation.

A. Yes, sir.

Q. Okay. The next line says, "Could you please fax me at 908-298-5908 a list of the investigators who

participated in," and then it has the numbers of a couple protocols.

Are you familiar with what's meant by a "list of investigators"?

A. Yes, sir.

Q. And what do investigators do relative to clinical studies?

A. These are the physicians, typically in academia, who enroll their patients in the clinical trial and follow the data and record the data for those investigations.

Q. Is learning who the investigators were something you would generally try to learn during due diligence?

A. Yes, it's very important, sir, yes.

Q. And why is it important?

A. Well, because the quality of the trial is really a function of the protocol and of the investigators who conducted the protocol, and so you'd like to know that these were reputable people, you'd like to know -- recognizing that phase III trials particularly are really the -- perhaps the most important marketing documents, even though they have an important regulatory meaning, that you'd like to feel that the investigators that had been enrolled in the

study are the sort of thought leaders that could then go on and represent the drug in things like meetings and so on after you've marketed it. So, it's important.

Q. And in this letter, two months after Mr. Audibert concluded his evaluation of Niacor-SR, he's now requesting this list of investigators. Is that correct?

A. That's correct.

Q. And do you know whether he had any of this information on who the investigators were on the clinical trials prior to -- prior to completing his evaluation?

A. I think not, sir.

Q. In this package, if we could just quickly look at three documents, which I believe Ms. Shores indicated were the protocols. If you could look at --

Your Honor, we don't have these electronically. If you would like a copy of this, I can see if Schering still has their copies from yesterday. I don't have additional copies.

JUDGE CHAPPELL: The protocols that were discussed on cross?

MR. SILBER: Yes.

JUDGE CHAPPELL: I don't need those.

MR. SILBER: Okay, thank you, Your Honor.

BY MR. SILBER:

Q. Dr. Levy, if you could turn to SPX 130.

A. SPX 1 -- yes, okay.

Q. Okay. And is this one of the protocols Ms. Shores asked you whether you had seen?

A. Yes, it is.

Q. Okay. Can you look at SPX 131?

A. Yes.

Q. And is this one of the protocols Ms. Shores asked you if you had seen?

A. Yes, it is.

Q. Okay. And then towards the back, if you can look at SPX 264 and tell me whether this is another protocol Ms. Shores asked if you had seen.

A. Yes, it is.

Q. Do you know whether Mr. Audibert had these when he did his evaluation?

A. I don't believe so, sir.

Q. Would it have been relevant to see these in doing an evaluation of Niacor-SR?

A. Yes.

Q. And why is that?

A. As I said a moment ago, the most important thing for a drug, particularly a drug that's late stage

like this, is -- you know, would be the clinical trial data, and those data are not particularly interpretable without knowing clearly what the protocol was to have generated those data.

Q. Let's turn in here to SPX 245.

A. 245, okay.

Q. Do you recall -- let me get this up on the ELMO.

Do you recall Ms. Shores showing you this document?

A. Yes, I do.

Q. And what is the date of this document?

A. August 21st, '97.

Q. So, again, this is about two months after Schering paid $60 million for Niacor-SR?

A. Yes, it is.

Q. And it's a memorandum from Mr. Audibert. Is that correct?

A. Yes, it is.

Q. And it's to a Dr. Bill Carlock?

A. Yes, it is.

Q. And do you recall that Ms. Shores indicated that Dr. Carlock was involved in manufacturing issues?

A. Yes, I do.

Q. Okay. So, does this document indicate that

there was some activity going on two months after Schering evaluated Niacor-SR relating to manufacturing activities or manufacturing review?

A. Well, there was a request -- I don't know if any activities actually went on. There was a request for some activity to ensue.

Q. Okay. In your experience, is such manufacturing review generally done during due diligence rather than after you pay for the drug?

A. Yes.

Q. And here, it appears as though this was being done after the money was paid for the drug.

A. It appears so.

Q. And in your direct testimony, after going through your valuation process chart, I believe you provided some testimony on whether there was any manufacturing review during Mr. Audibert's five-day evaluation. Do you recall that?

A. Yes, I do.

Q. And do you recall what your testimony was on that point?

A. I saw no evidence of there being any such review.

Q. Paula, if you could pull up CX 1092, and this is also in this package of materials, Dr. Levy. If we

could go to the fifth page of this document.

A. Is that 940?

Q. Yeah, the page number is SP 002940.

Do you recall Ms. Shores showing you this document?

A. Yes, I do.

Q. And what is the date of this document?

A. August 21st, 1997.

Q. And this is from Mr. Audibert to Mr. Kapur. Is that correct?

A. Yes, it is.

Q. Okay, and if we could pull up the big paragraph in the middle of the memo.

Okay, the first line says, "As previously discussed, we have been trying to arrange a trip to Upsher-Smith for mid-September in order to review the regulatory and clinical documents."

Do you see that, Dr. Levy?

A. Yes, I do.

Q. Is such regulatory and clinical review generally done during due diligence?

A. Yes.

Q. And here, we're two months after the evaluation was completed and the $60 million was paid. Is that correct?

A. Yes.

Q. And do you recall whether there was any regulatory or clinical review done on Niacor-SR during Mr. Audibert's evaluation?

A. As far as I know, there was not.

Q. Do you find it unusual based upon your experience in the industry that the due diligence on regulatory and clinical issues would be done two months after the money was paid for the drug?

A. No -- yes, I find it unusual.

Q. And why is that?

A. You usually want to check out the merchandise before you buy it, not afterwards.

Q. If we could go to the bottom of this paragraph, the second to last sentence says, "Mark," and I believe that's a reference to Mark Halvorsen of Upsher, "also indicated that no clinical data would be available until late October and even then, it will probably be just individual reports and not the ISS or the ISE."

Do you see that?

A. Yes.

Q. Can you remind us what kind of timetable Schering was on to get Niacor-SR to Europe?

A. The initial plan that Mr. Audibert was presented and I think was presented to the board of

directors subsequent to that was that they had intended to have approval in the European Union by the end of 1998, which would mean that they would have had to have filed the dossier no later than the middle of 1998.

Q. And here in this document, it's talking about no clinical data being available until late October, which is about three or four months after the deal was concluded. Is that correct?

A. Yes.

Q. How would that delay in providing the clinical data from Upsher to Schering impact on Schering's time lines for getting Niacor-SR to Europe?

A. It would have delayed it.

Q. And how is that significant to Schering?

A. Well, Schering was -- was relying on having these data to form the bulk, the basis for its filings in the European Union, and a delay, of course, would have not provided them that information and those data. It is within Schering's capability to have generated those data themselves. I think there was some testimony during my cross earlier that it's not requisite to have U.S. data to file in the European Union. It just would have been time.

Schering would have had to have started the trials all over again, and it would have taken them

two, three, four years to have generated the requisite data. So, they certainly would have missed their time line.

Q. Okay. As this document shows and many of the other documents that Ms. Shores showed you, Mr. Audibert was involved to some degree in Schering's efforts after the deal was concluded. Is that correct?

A. Yes, he was.

Q. Do you have an understanding as to what Mr. Audibert's role was after the deal was concluded?

A. I'm not sure what "understanding" means. He seemed to be the internal enthusiast for the drug and the -- and he seemed to be doing everything. So, I don't -- I don't know what -- you know, your question was what my understanding is, and he just seemed to be -- to have some involvement, but I'm not sure that I know what that really was.

Q. Okay, let me try to ask a more specific question. It may be easier.

Was he the project leader?

A. Well, there's, you know, ambiguity about that. I don't think so, because I -- I'm not sure about this, but I believe in his own deposition -- and you'll probably be able to refresh my memory on this -- I -- because I specifically looked for the existence of a

project team or any semblance of one, I remember this part of his testimony, and I think that he was asked, if I'm not mistaken, whether he was the project leader, and he said no, I don't do that sort of stuff, or something to that effect.

Q. Let me show you some testimony by Mr. Audibert. This is at his September 21st, 2000 investigational hearing, and let me just start, this is at page 122, line 22, and I am just going to read this testimony to you:

"QUESTION: Okay. The second sentence of the note from Mr. Kapur to Mr. Lauda says, 'Although global marketing is fully responsible for developing and registering Niacor-SR, please instruct your designated project leader to set up a quarterly briefing for me on the development status so that I can update Ian Troup, president of Upsher-Smith --'" I'm sorry, let me pull up that testimony -- "'regarding timely progress towards registration and keep our relationship with Upsher on track.'

"Do you see that?

"ANSWER: Yes.

"QUESTION: Did you have an understanding that global marketing was fully responsible for developing and registering Niacor-SR?

"ANSWER: I don't -- I don't remember what I thought when I saw this.

"QUESTION: Well, now, do you recall that you had -- that global marketing was fully responsible for developing and registering Niacor-SR?

"ANSWER: Global marketing is not responsible for registering products, so as I read it today, this is what's confusing.

"QUESTION: You just don't understand what this means?

"ANSWER: That's correct.

"QUESTION: Did you have a designated project leader to your knowledge for the Niacor-SR?

"ANSWER: I'm not sure of whether he meant me, but I'm not sure there was a designated project leader.

"QUESTION: I'm not sure I understood your answer. Do you know if there was any designated project leader in global marketing for this product?

"ANSWER: Well, I don't know what Mr. Kapur means by the term 'designated project leader.'

"QUESTION: Okay. Did you consider yourself a designated project leader for Niacor-SR?

"ANSWER: I guess de facto."

Is this the testimony you were referring to?

A. Yes, it is, sir.

Q. And what does this indicate to you about Mr. Audibert's role after the deal was concluded as a project leader?

A. I don't -- I'm not sure what it means to me. It -- I mean, I -- I'm not sure how to testify to this. I sort of feel sorry for the guy. I think he had this whole thing on his shoulders from -- it seemed from start to finish, and now he's put in another role to which he's not accustomed, and now he's suddenly, to use his term, de facto project leader on a project team of one. So, I don't know what -- I'm not sure how to interpret it other than to feel bad for Mr. Audibert.

Q. Okay, Paula, if you could put up the post-deal conduct slide, which was marked for identification as CX 1610.

Dr. Levy, if you'll recall, this is the slide that we went through on your direct summarizing the third part of your opinion that post-deal the parties were not serious about developing and marketing Niacor-SR.

A. Yes.

Q. Now, in Ms. Shores' cross examination, she walked you through several documents of communication after the deal was concluded. Do you recall that?

A. Yes, I do.

Q. Did those documents -- what I want to do is go through these points one by one.

A. Okay.

Q. Did the documents she showed you change your first bullet point here on the project team? Did it change your opinion?

A. No.

Q. Why is that?

A. I think she showed me some attempts from -- from poor Mr. Audibert to get some relevant people to participate in at least evaluating this product, and I saw no evidence that he even was successful in getting those people to do anything, but that certainly was not what I would have considered anything even vaguely resembling a project team.

Q. What about your second point here about meetings between Upsher-Smith and Schering to coordinate development, address problems, share information, did the documents Ms. Shores showed you change your opinion here?

A. No, it did not.

Q. And why is that?

A. I don't think there were meetings between the parties to address problems, to do any of that. I mean, I think the -- as I think I testified on my

direct testimony, it still amazes me -- I mean, it really does -- why the parties never talked about that simple pharmacokinetic problem, which Schering could have solved for them in a moment. And so, simply stated, I see no evidence to cast any doubt on that second point.

Q. Okay. And the third point I don't think Ms. Shores showed you any communications regarding, protocols regarding for EU clinical studies, so let's jump to the last point, which is full disclosure by Upsher-Smith to Schering-Plough regarding development problems and change.

Did any of the documents she showed you -- and for that matter the documents Mr. Curran showed you about Upsher's work on clinical studies -- did that impact on your opinion here?

A. No. As a matter of fact, all the while Mr. Curran was taking me through a very interesting, you know, binder of documentation of that, I literally kept saying to myself, where's Schering in this? You know, they were having communications with their CRO, they were having communications with various people, and in not one of them was a single person from Schering part of the conference call or, as far as I could see, informed of the call, which to me is just -- it's

mind-boggling.

MR. SILBER: That's all I have, Your Honor.

JUDGE CHAPPELL: Okay.

Recross?

MS. SHORES: Just briefly.

THE WITNESS: Mr. Silber, can I give you this back?

MR. SILBER: Just put it back there.

THE WITNESS: Okay, thank you.

RECROSS EXAMINATION

BY MS. SHORES:

Q. Good afternoon, Dr. Levy.

A. Hi, Ms. Shores.

Q. In your redirect just a second ago, you said something about the fact that you didn't consider Schering's anticipated research and development costs when you were evaluating the other Schering deals. Is that correct?

A. Yes, that's correct.

Q. And that's because I think you said that you consider research and development to be like human resources, right, that's something that's included within overhead? Is that --

A. No, no, that's not what I said. I mean, if I implied that -- I don't think I used the term

"overhead."

Q. Well, you talked about human resources, didn't you?

A. Yes. I have a tendency maybe when I'm up here for a while to be more flippant than I should be, and I apologize to you and the Court for that, but the R&D expenses, the money that a company is going to spend on developing a drug, whether this drug be discovered inside in its own discovery operation or outside and hence be in-licensed is an expense that the company is accustomed to, and the expenses are going to vary from product to product and type to type, and I don't think that when a company is deciding how much of an up-front payment it's going to make that's a -- that's a parameter that it considers.

Q. Pharmaceutical companies frequently out-source research and development, do they not?

A. As I said, that -- that certainly has been the case and continues to be the case with the smaller and the medium-sized companies. The larger companies have gone to doing it more and more in the last decade, and I think that they now, as I have my own perception of what's going on in the industry, are becoming a little bit more disenchanted with the quality of the work that many of the CROs do, so they tend to be bringing things

more back in-house now. But the answer to your question, in fairness, is yes.

Q. Okay. And even if Schering were anticipating with respect to these various deals doing the research in-house, I take it that would prevent the researchers from doing work on other products, right?

A. I don't think "prevent" in the right word. You know, I mean companies are usually able to expand their research budget if they have an opportunity. You know, I don't think that it -- that a company like Schering-Plough, which is a very fine company, would -- would ignore the opportunity to develop a major drug because it might put a little hit on its bottom line.

Q. And expanding a research and development budget, that requires more money, doesn't it?

A. Or a re-allocation of money.

Q. Well, you're not saying, are you, Dr. Levy, that the fact that in this case Upsher-Smith was responsible for the bulk of the research and development efforts had no value to Schering, are you?

A. Well, I'm not sure that I agree with the first part of your statement, in that as I understand it, Schering-Plough was responsible for all the expenditure, registration of the document -- of the compound in its territories.

Q. Right, but as I think you testified, that was going to be based on the clinical work that Upsher had done, right?

A. Some of it was going to be based on that, yes.

Q. And so my question is, do you think that the fact that Upsher-Smith was doing that clinical work and not Schering had any value to Schering?

A. The fact that Upsher had done the work?

Q. Yes, and was continuing to do the work, as we've seen.

A. Yes, I think that's the sort of thing that's built into the milestones and the royalties. That's why -- that's what brought them to the table in the first place.

Q. I'm going to change topics on you. When Mr. Silber was showing you that bar chart, do you recall that?

A. Yes.

Q. This is the one with the other Schering deals?

A. Yes.

Q. None of those drugs -- and again, those were the other deals that you compared the Niacor deal to, right?

A. Yes.

Q. None of those deals involved

cholesterol-lowering drugs, did they?

A. No.

Q. And finally, Dr. Levy, you gave some testimony just a few minutes ago about what the FDA was saying with respect to pharmacokinetic tests and various other things. Do you recall that?

A. Yes, sir.

Q. You can't speak for what the FDA would do with Niacor-SR, right?

A. I -- the reason I'm hesitating again is, of course I can't. I don't speak for the FDA. So, the direct answer is -- but I think that people -- you know, I'm hired and I'm testifying as an expert with considerable experience with the FDA's conduct, and so I have -- you know, I may have opinions on what I think they might do, but only they can say what they were going to do.

Q. And you can't say that what -- you can't speak for the FDA as to how they would view the evidence that you say was suggestive of liver toxicity, right?

A. No, as I said, I don't -- I, of course, cannot speak for the FDA, to use your exact words.

MS. SHORES: Thank you very much. I have nothing further.

JUDGE CHAPPELL: Recross from Upsher-Smith?

MR. CURRAN: Yes, even briefer, Your Honor.

RECROSS EXAMINATION

BY MR. CURRAN:

Q. Dr. Levy, in your report, you based your conclusions on -- in part on the following statements, correct: "Upsher-Smith had performed preliminary pharmacokinetic studies with a single dose of Niacor-SR, but the FDA demanded that the studies be performed with repeat doses of the drug.

"Without the generation of consistent and reliable multiple-dose pharmacokinetic data, Upsher-Smith could not win approval of Niacor-SR in the U.S. or other major markets of the world."

Correct?

A. Yes, I wrote that.

Q. Okay. Now, sir, a moment ago Mr. Silber was showing you a document dated February 24, 1997. Do you still have that in front of you?

A. Is this the document, sir?

Q. Yeah, that's the one you asked for a hard copy of.

A. Yes.

Q. And sir, I believe you stated that in the minutes included in this document, Dr. Halvorsen of Upsher-Smith was advocating a single-dose study rather

than a multi-dose study. Do you remember giving that testimony a moment ago?

A. That is -- I don't think that's what I said. I think I said that it seemed that the Upsher-Smith representatives were attempting to negotiate with the FDA about what the FDA had been telling them for the past four or five years.

Q. Okay. Sir, in fact, the representatives of Upsher-Smith succeeded in those negotiations, right, because the cover letter after that meeting states, "Also enclosed for your review is a proposed protocol for the single dose, 3-way crossover, pharmacokinetic evaluation of niacin and its metabolites in urine (see Attachment 2), as agreed to during the February 5, 1997 meeting."

A. Yes, I see that.

Q. Did I read that correctly?

A. Yes.

Q. Sir, you don't know, staying on the subject of pharmacokinetic studies, you don't know what type of pharmacokinetic study or data would have been required in connection with the filing of a new drug application in Europe for Niacor-SR, correct?

A. Oh, that's a fair comment, yes.

Q. So, it's correct?

A. Yes.

Q. Okay. And sir, as far as you're concerned, a multi-dose pharmacokinetic study and a single-dose pharmacokinetic study, neither one is particularly more difficult than the other; it's just a little bit more work, correct?

A. No, that's not correct.

Q. Okay. Sir, at your deposition, did you or did you not give the following testimony:

"QUESTION: Is a multi-dose pharmacokinetic study more difficult than a single-dose pharmacokinetic study?

"ANSWER: I don't think either of them are particularly difficult. It's just it's a little bit more work."

Did I read that correctly, sir?

A. Yes, and I don't think that contradicts what I just said.

Q. Sir, what is GIGO again?

A. Garbage in, garbage out.

MR. CURRAN: Nothing further, Your Honor.

JUDGE CHAPPELL: Dr. Levy?

THE WITNESS: Yes, sir.

JUDGE CHAPPELL: What does it mean when two drugs are bioequivalent?

THE WITNESS: That's a term that's used principally in reference to generics and the filing of what you've heard testimony about, an abbreviated new drug application. What it says is is that the second drug, when administered, produces the same blood levels in approximately the same time and that these blood levels persist for approximately the same time.

JUDGE CHAPPELL: So, effectively the two drugs are interchangeable?

THE WITNESS: Well, what the generic laws allow, what the ANDA laws allow is that they rely on the first drug, the branded drug, as having established safety and efficacy, and then the rule is that the second drug need only come along and do two things.

First, it has to prove bioequivalence, as you just asked me, and the second thing is that it has to produce the same sort of somewhat -- you know, somewhat demanding CMC or chemical manufacturing control section. That is, the generic company is relieved from having to do the clinical trials, but it still has to dot all the Is and cross all the Ts on the manufacturing component as if it were an NDA, as if it were a branded drug.

JUDGE CHAPPELL: So, if my doctor prescribed erythromycin --

THE WITNESS: Yes, sir.

JUDGE CHAPPELL: -- 1500 milligrams a day, a bioequivalent generic could be prescribed, and it would be the same drug essentially?

THE WITNESS: As usual, I have to -- it is -- it is essentially the same drug. The reason I'm trying to give you a useful answer is the laws state that the active component, that is, in this case the erythromycin has to be the same, but the so-called excipients or the nonactive components -- you take a pill, you know, a pill has the active stuff in it, but then there's all sorts of stuff that you need to compress the pill, to put it together, and those can vary.

And so the drug that you're taking is not identical. It is identical only in that the active ingredient is identical. And sometimes a generic is a total copy, but -- I'm sorry to give you more of an answer than you probably wanted, but that's -- that's what it is.

JUDGE CHAPPELL: Should a patient be concerned if a generic is substituted for the brand drug?

THE WITNESS: That's a very interesting question, and the simple answer is I believe so, yes.

JUDGE CHAPPELL: Let me ask you this: What's

the difference -- let me restate that.

What does it mean when two drugs are therapeutically equivalent?

THE WITNESS: That I think --

JUDGE CHAPPELL: And if that's beyond your area of expertise, just let me know.

THE WITNESS: Everything's beyond -- no, when two drugs are therapeutically equivalent, I think it means that they have the same efficacy, so that -- for instance, the statins, which we've talked about, you know, over the last few days, there are certainly differences between the statins, and some are probably a little bit better than others, but for the most part, the newer statins are more or less therapeutically equivalent, and that means they're the same in safety and efficacy.

JUDGE CHAPPELL: Thank you.

Any questions -- any follow-up questions based on my questions?

MR. SILBER: No, Your Honor.

MR. CURRAN: I have one question, Your Honor.

JUDGE CHAPPELL: Proceed.

FURTHER RECROSS EXAMINATION

BY MR. CURRAN:

Q. Dr. Levy, two products can be therapeutically

equivalent without being bioequivalent, correct?

A. Yes, that's certainly the case, because I think that -- for instance, the example I used, the statins, I don't -- I have not seen the pharmacokinetic study -- pharmacokinetic data on either of them, but the answer is yes. I'm sorry to be so long-winded.

MR. CURRAN: Nothing further, Your Honor.

JUDGE CHAPPELL: Anything else?

MS. SHORES: No, Your Honor.

MR. SILBER: No, Your Honor.

JUDGE CHAPPELL: Dr. Levy, you're excused. Thank you for your time.

THE WITNESS: Thank you, sir.

JUDGE CHAPPELL: Complaint counsel, call your next witness, please.

MS. BOKAT: Your Honor, complaint counsel call as our next witness Joel Hoffman. He will be examined by David Narrow, one of complaint counsel. I wanted to raise one scheduling issue with Your Honor before Mr. Hoffman begins to testify, if I may.

JUDGE CHAPPELL: Do we need to do this on the record?

MS. BOKAT: Not necessarily.

JUDGE CHAPPELL: Let's go off the record while everybody's shuffling around.

(Discussion off the record.)

JUDGE CHAPPELL: Ms. Bokat, just briefly state your issue regarding witness Hoffman.

MS. BOKAT: Yes, Your Honor. Joel Hoffman is here in the courtroom ready to testify. He is prepared to stay late this evening to conclude his testimony, but he is unavailable tomorrow and Friday because he will be in New Hampshire teaching a law school class at Franklin Pierce Law School.

JUDGE CHAPPELL: Okay, Mr. Nields, it's my understanding that you have no objection to going late if you're allowed to finish your cross before you leave. Is that correct?

MR. NIELDS: That is correct, again, depending -- if direct finishes by 5:30 or so, that will be -- that will be doable.

JUDGE CHAPPELL: Mr. Curran, no objection to going late?

MR. CURRAN: No objection, Your Honor.

JUDGE CHAPPELL: Why don't we press on. Let's see where we're at as the day progresses. So, go ahead and call your next witness.

MS. BOKAT: I call Joel Hoffman. Thank you, Your Honor.

MR. CURRAN: Your Honor, Mr. Gidley will be

handling this witness on behalf of Upsher-Smith.

JUDGE CHAPPELL: Okay, thank you.

Raise your right hand, please.

Whereupon--

JOEL E. HOFFMAN

a witness, called for examination, having been first duly sworn, was examined and testified as follows:

JUDGE CHAPPELL: Be seated.

State your full name for the record, please, sir.

THE WITNESS: My name is Joel E. Hoffman.

JUDGE CHAPPELL: You may proceed.

MR. NARROW: Thank you, Your Honor.

DIRECT EXAMINATION

BY MR. NARROW:

Q. Mr. Hoffman, you were asked by complaint counsel in this matter to serve as an expert witness, correct?

A. Correct.

Q. Before we go through your qualifications, would you very briefly summarize what you were asked to provide your expert opinion about in this matter?

A. Yes. I was asked to provide an expert opinion on four questions arising under the Hatch-Waxman Amendments to the Federal Food, Drug and Cosmetic Act.

All of the questions related to the legally permissible FDA approval date for generic versions of Schering's patented drug K-Dur, which is potassium chloride 20 milliequivalent extended release tablets, and for simplicity, as I go on, I will probably refer to the -- to that drug as the drug in question or the relevant drug.

Q. Okay. Were you asked to provide an opinion regarding -- relating to Upsher-Smith's entitlement to 180-day exclusivity under the Hatch-Waxman Act on certain dates?

A. Yes, I was, on -- as of June 17th, 1997 and January 23rd, 1998.

Q. Okay. And what were you asked about Upsher-Smith's entitlement to 180-day exclusivity on those dates?

A. I was asked whether on each of those dates there was a substantial -- well, let me take them one at a time.

As to June 17th, 1997, I was asked whether on that date Upsher -- Upsher-Smith -- there was a substantial uncertainty as to whether Upsher-Smith would be entitled to 180-day exclusivity as against other generic applicants for the same drug if it were to settle Schering's patent infringement case against

it without a judicial determination that the patent in question was invalid or not infringed.

The second question I was asked was essentially the same question speaking as of January 23rd, 1998, whether Upsher on that date, having previously settled its patent infringement suit with Schering without a finding that the patent in question was invalid or noninfringed, whether on January 23rd, 193 -- 1998 there was substantial uncertainty whether Upsher was entitled to exclusivity.

Q. Okay. Were you asked for your opinion relating to the triggering of 180-day exclusivity under the Hatch-Waxman Act?

A. Yes, I was.

Q. And what were you asked in this regard?

A. I was asked for my opinion whether on each of those same two dates, June 17th, 1997 and January 23rd, 1998, whether there was a substantial possibility that any 180-day exclusivity period to which Upsher was entitled could be triggered by a court decision relating to the patent in question in patent litigation other than that brought by Schering against Upsher.

Q. Okay. And with regard to -- you were asked that with regard to January 23rd?

A. Yes, I was asked that with respect to both

dates.

Q. Okay. And were you asked for your opinion on the current status of Upsher-Smith's entitlement to 180-day exclusivity?

A. Yes, I was.

Q. And what were you asked in that regard?

A. I was asked whether in my opinion Upsher was currently entitled to 180-day exclusivity for the drug in question.

Q. And are you prepared today to offer your opinions as to the answers to the questions that you were asked?

A. I am.

Q. Okay. Now, we'll be going into these in more detail later. In order for the Court to better understand where we're going, could you briefly summarize your conclusions with regard to the questions that were raised, first with regard to Upsher-Smith's entitlement to 180-day exclusivity on June 17th, 1997?

A. My opinion is that on June 17th, 1997, there was substantial uncertainty whether Upsher would be entitled to 180-day exclusivity if it were to settle Schering's patent infringement suit against it without a judicial determination that the patent in question was invalid or not infringed.

Q. And could you please summarize your conclusion about Upsher's entitlement to 180-day exclusivity on January 23rd, 1998?

A. My opinion is that on January 23rd, 1998, Upsher had a -- by that point settled the infringement suit by Schering without a judicial determination of patent invalidity or noninfringement, that there was equal or greater uncertainty as to whether Upsher was entitled to exclusivity.

Q. Okay. And would you please summarize your conclusions regarding the triggering of any 180-day exclusivity to which Upsher was entitled as of June 17th, 1997 and January 23rd, 1998?

A. My opinion is that on June 17th, 1997, there was no substantial reason to believe that a judicial determination in third-party litigation -- that is, not involving Schering's suit against Upsher-Smith -- there was no substantial reason to believe that a decision in such litigation would trigger Upsher-Smith's exclusivity, but on January 23rd, 1998, there had come to be a substantial possibility that a decision in a third-party infringement litigation would trigger Upsher's exclusivity.

Q. Okay. And would you please summarize your conclusion regarding the current state of Upsher's

entitlement to 180-day exclusivity?

A. My opinion is that Upsher currently, unquestionably, is entitled to 180-day exclusivity.

Q. Okay. Before we go into more detail, I'd first like to go over your qualifications to render an expert opinion regarding the FDA and the Hatch-Waxman Act and concluding that there's a 180-day exclusivity period.

Mr. Hoffman, what is your profession?

A. I'm a lawyer.

Q. And where did you attend law school?

A. Yale Law School.

Q. And when did you graduate from law school?

A. 1960.

Q. And with what degree?

A. The LLD degree as it was then known.

Q. And where are you admitted to the Bar?

A. The District of Columbia and State of New York.

Q. Would you please briefly describe your law practice employment history, where you've worked and when?

A. From 1960, when I graduated from law school, until 1963, I was in the Antitrust Division of the U.S. Department of Justice under the -- I believe it was called the Honor Recruitment Program for Honor Law Graduates or the Attorney General's Recruitment Program

for Honor Law Graduates. I was in the Appellate Section of the Antitrust Division, where I was responsible for briefing both antitrust and administrative agency appeal cases in the courts of appeals, three-judge district courts, and as far as briefing goes, in the Supreme Court.

Q. And after your tenure at the Justice Department?

A. After three years at the Justice Department, I went into private practice with the Washington law firm that came to be known as Wald, Harkrader & Ross, which is now defunct. I practiced there until 1985 as a partner from 1968. In 1985, I became a partner at the Washington office of Sutherland, Asbill & Brennan.

Q. And where do you currently practice?

A. I am currently of counsel, semi-retired, at Sutherland, Asbill & Brennan, which is where I practice to the extent I currently do.

Q. And what areas of law have you specialized in during your legal practice?

A. Generally speaking, federal administrative and regulatory law throughout the period, and beginning in about 1964, FDA regulatory law. From about 1969, FDA regulatory law has been my primary field of practice.

Q. And has that included Hatch-Waxman law?

A. Yes. My practice has included a variety of issues arising under many if not most of the provisions of the Food, Drug and Cosmetic Act, including specifically issues arising under the Hatch-Waxman Amendments.

Q. Without specifying individual names, would you please describe who have been your clients in the pharmaceutical area?

A. My clients have included a number of research-based, that is to say, brand name pharmaceutical companies, pharmaceutical manufacturers, generic pharmaceutical manufacturers, a trade association of brand name pharmaceutical manufacturers, national organizations in the pharmacy profession and in the medical profession.

Q. And what types of work have you done for your clients?

A. I've represented these clients in litigation against each other and against FDA. I have advised them on compliance issues. I would advise them on legal questions that have arisen under various provisions of the Food and Drug Act, including specifically Hatch-Waxman issues. I have assisted in drafting proposed legislation in the FDA regulatory area.

Q. Have you held any academic posts or affiliations in your areas of legal practice?

A. Yes, I have.

Q. And what academic posts or affiliations have you held?

A. Since 1998, I've been adjunct professor of law at George Mason University Law School, teaching FDA regulatory law, and since 1997, at Franklin Pierce Law Center in New Hampshire teaching the same subject.

Q. Okay. And have you lectured at other law schools?

A. I have lectured in the FDA regulatory law courses at New York University Law School and at the University of Mississippi Law School.

Q. How did it come about that you lectured at the University of Mississippi Law School?

A. Well, it was in the late seventies or early eighties, and a client of mine at that time, a large pharmaceutical manufacturer, had a major headquarters in a large city not far from the University of Mississippi. The client then funded or subsidized the costs of giving an FDA regulatory law course there. I was asked by people in the general counsel's office or the law department of the company to do a guest lecturer shot as part of the course.

Q. And what pharmaceutical company was it that invited you to be a guest lecturer at the University of Mississippi Law School?

A. Well, actually it was Schering-Plough.

Q. Please tell us about any industry or other presentations that you've made on FDA regulatory law.

A. I've given upwards of a dozen presentations at various you might say continuing legal education conferences on FDA regulatory subjects sponsored by the American Bar Association, the Food and Drug Law Institute, now known as FDLI, and I believe also the Practicing Law Institute.

Q. What is FDLI?

A. FDLI is an independent, nonprofit but industry-funded organization dedicated to presenting educational programs and publishing educational works or reference works on the subject of FDA regulation. Many of its conferences are jointly sponsored by the U.S. Food and Drug Administration.

Q. Have any of your presentations been published?

A. Yes, they have.

Q. And where have these presentations been published?

A. They -- many of them have been published in the Food -- what is now known as the Food and Drug Law

Journal, which is the specialized law review published by FDLI; in the Administrative Law Review, which is the law journal published by the ABA Section on Administrative Law and Regulatory Practice; and also in The Business Lawyer, which is the ABA Business Law Section's law journal.

Q. And what is the reputation in the professional area of those publications in which your presentations have been published?

A. I think that these are -- particularly the Food and Drug Law Journal is regarded as the primary vehicle for scholarly articles and other presentations in the food and -- in the FDA regulatory area.

Q. Have you published or contributed to any books in your field?

A. Yes, I have.

Q. And what books have you published or contributed to?

A. I should also add to my last answer that I believe the Administrative Law Review is also very widely regarded as a prominent vehicle for scholarship in the field of federal administrative law generally.

As far as books are concerned, I contributed the chapter on FDA administrative procedures to the treatise on fDA regulation published by FDLI. It's --

the current edition is a two-volume edition. I contributed the chapter in the current and all prior editions, going back about 15 years.

Q. And what is the title of that publication?

A. The current title is Fundamentals of Law and Regulation, by which they mean actually fundamentals of FDA law and regulation.

Q. And what is the reputation of Fundamentals of Law and Regulation in your profession?

A. It's one of the primary research tools in the field.

Q. Please describe the professional leadership positions you have held in your field.

A. I have served several terms as chair of the Food and Drug Committee of the ABA Section of Administrative Law and Regulatory Practice. In that section, I also served a term as a member of the council, of the governing council of that section. I served a term as vice-chair of the Food and Drug Committee in the ABA Business Law Section.

Q. Okay. Please describe any honors that you have received in your area of professional practice.

A. In I believe 1999, I received FDLI's Distinguished Leadership and Service Award.

Q. And for what did you receive that award?

A. For contributions over a number of years to FDLI's educational mission.

Q. Thank you.

Your Honor, based on Mr. Hoffman's more than 30 years of experience practicing administrative and FDA regulatory law, his practice of Hatch-Waxman Act law since that law's enactment in 1984 and his extensive law school and professional teaching, published writings and leadership positions and honors in his field, we tender him as an expert in the field of FDA regulatory law and procedure, including the Hatch-Waxman Act, and as qualified to give his expert opinions regarding all aspects of the operation, interpretation and application of the Hatch-Waxman Act, including the Act's 180-day exclusivity provisions.

MR. NIELDS: No objection.

MR. GIDLEY: Your Honor, we have no objections on behalf of Upsher-Smith as to this witness' experience and expertise in FDA regulatory matters. We would note for the record, Your Honor, that we think in terms of pure questions of law, those are entirely the province of this Court and not this witness. So, I simply want to note that for the record.

JUDGE CHAPPELL: Did you move -- did you just make a motion, Mr. Narrow?

MR. NARROW: Yes, I did.

JUDGE CHAPPELL: Hearing no strenuous objection, the motion is granted.

MR. NARROW: Thank you, Your Honor.

BY MR. NARROW:

Q. Now, Mr. Hoffman, you have stated that you were requested by complaint counsel in this matter to serve as an expert witness, correct?

A. That's correct.

Q. Have you ever testified as an expert witness before today?

A. No, I have not.

Q. And what are you being paid for your services?

A. I'm being paid my usual billing rate, which is $450 an hour.

Q. Now, you stated earlier that you were asked by complaint counsel to address several questions relating to the Hatch-Waxman Act and its 180-day exclusivity provision. Is that correct?

A. Yes.

Q. Okay. Are questions regarding the Hatch-Waxman Act and its 180-day exclusivity provision something that you commonly have been called upon to address in your practice?

A. I have been called on frequently to address

them.

Q. Okay. Please describe generally what you did in order to arrive at your expert opinions in the present matter.

A. Well, the first thing I did was to review the relevant statutory provisions and the provisions of FDA regulations. I reviewed the various court decisions that have interpreted the provision and the regulations. I reviewed other materials generated or issued by FDA on the subject. I reviewed press reports, media reports, of developments in the -- on that -- on that subject.

Q. Are the materials that you consulted in reaching your opinions in the present matter the types of materials upon which you typically rely in forming an opinion about the FDA and Hatch-Waxman Act issues, including the Act's 180-day exclusivity provisions?

A. Yes, they are.

Q. Okay. Was the analysis that you performed in order to arrive at your expert opinions in this matter the type of an analysis that you'd typically perform in providing advice and analysis on Hatch-Waxman Act issues to your clients?

A. Yes, they are.

Q. And are you prepared today to give your expert

opinion on the questions you were asked to address by complaint counsel?

A. I am.

MR. NARROW: Your Honor, we will now be going into the substance, and it may be a convenient time to hand out binders that I have of the exhibits that will be used by Mr. Hoffman in his direct testimony.

JUDGE CHAPPELL: You may do so.

MR. NARROW: May I approach?

JUDGE CHAPPELL: Yes, you may.

Mr. Gidley, just so we have an understanding, I heard your objection, and I'm not going to give you a running objection on legal opinions, so you must object if you need to during the testimony.

MR. GIDLEY: Understood, Your Honor.

JUDGE CHAPPELL: Mr. Narrow, what's the status of these exhibits? Have they been provided to opposing counsel? Have they been admitted?

MR. NARROW: A number of them, the letters, which are CX 602, 595, 611 and 612 all were admitted on January 22nd. The two demonstratives, which are CX 1655 and 1656, which we will be using, have not yet been admitted, but copies have been provided to respondents' counsel. Three exhibits, CX 600, 636 and 605 and also CX 1653 have not yet been admitted into

evidence.

JUDGE CHAPPELL: Okay. And do you intend to offer them for admission?

MR. NARROW: Yes, for all the ones that have not previously been admitted, I do intend to move their admission as they are used.

JUDGE CHAPPELL: You may proceed.

MR. NARROW: Thank you.

BY MR. NARROW:

Q. Now, in order to place the Hatch-Waxman Act, including its exclusivity provisions, in context, I first want to ask you a series of questions about the federal regulatory process for drugs to be approved to come to market.

First of all, what is the FDA's role in the approval of drugs?

A. FDA approval is required for any new drug to be legally marketed in the United States.

Q. Now, is FDA approval required for both branded and generic prescription drugs?

A. Yes, it is.

Q. And what is a branded drug?

A. A branded drug or sometimes known as a pioneer drug, an innovator drug, is typically the first -- the first drug product containing the particular active

ingredient to be reviewed and approved by FDA.

Q. Okay. And what is a generic drug?

A. A generic -- a generic drug is, as I believe Dr. Levy testified a little while ago, is a drug product containing the same active ingredient but not necessarily the same inactive ingredients as the -- as the branded or -- brand name or pioneer drug.

Q. Okay. And what is the general approval process for new drugs?

A. For branded drugs or innovator drugs, the manufacturer is required to submit to FDA a new drug application or NDA containing a showing that the drug is safe and substantial evidence that the drug is effective for its intended uses, as well as complete information on the manufacturing processes that will be used.

Q. Okay. Very briefly, could you describe the process for FDA approval of generic drugs prior to the enactment of the Hatch-Waxman Act?

A. Prior to the enactment of the Hatch-Waxman Amendments, there was generally speaking, with some particular exceptions that are not relevant here, there was no separate process for the approval of generic drugs. A would-be generic drug manufacturer would have been required, was required at that time, to duplicate

or replicate the entire body of data showing safety and effectiveness that had been generated as to the active ingredient by the innovator manufacturer, as well as, of course, presenting its evidence of its own generic applicant's manufacturing processes.

Q. Okay. Would you briefly and generally describe the process of FDA approval of generic drugs since enactment of the Hatch-Waxman Act?

A. By virtue of the Hatch-Waxman Amendments, generic drug products do not need to duplicate the safety and effectiveness data that was the basis for approval of the active ingredient in the pioneer or innovator product. The generic applicant need only show that its product is bioequivalent to the active -- to the pioneer product containing the same active ingredient, plus -- plus its own -- evidence of its own manufacturing processes for approval.

Q. And what is bioequivalent?

A. As Dr. Levy explained earlier, bioequivalence -- when two drug products are bioequivalent, they -- it means they are absorbed into the bloodstream when ingested by a patient at the same rate and to the same extent, and Dr. Levy also mentioned, and remain at certain levels for the same period of time.

Q. Okay. Please describe the FDA's organizational division of responsibilities for review and approval of both NDAs, new drug applications, and ANDAs or abbreviated new drug applications since enactment of the Hatch-Waxman Act.

A. All of FDA's drug approval responsibilities, except for a class of drugs called biological products that's not relevant here, are handled by a unit within the agency called the Center for Drug Evaluation and Research or CDER. CDER is itself divided primarily into a number of so-called reviewing divisions, which are divided up according to the particular therapeutic category of drug involved, such as anti-infective drugs, gastrointestinal drugs, neuropharmalogical drugs and so forth. These divisions are responsible for reviewing full new drug applications submitted by -- for -- by innovator manufacturers for their products.

There is also in CDER a separate office called the Office of Generic Drugs, which is responsible for approving -- reviewing and approving abbreviated NDAs or ANDAs, which is the name given to the application for generic products since the Hatch-Waxman Amendments.

Q. Was the Office of Generic Drugs previously known by a different name or have some slightly different organizational status?

A. The Office of Generic --

Q. The Office of Generic Drugs, was it known by a different name after the Hatch-Waxman Act?

A. I'm sorry, that is -- I may have misunderstood your question. That is the current organizational scheme. Prior to Hatch-Waxman, there really wasn't -- wasn't much of any organization for generic drugs, because there really weren't very many.

Q. Okay. So, what responsibilities, if any, does the Office of Generic Drugs have or has it had since 1984 for the review and approval of new drug applications?

A. The full new drug applications for innovative products you mean?

Q. Correct.

A. None whatsoever.

Q. Okay. Are there different stages of FDA approval of an abbreviated new drug application or ANDA for a generic drug?

A. Yes, there are.

Q. And what are those stages of approval for an ANDA?

A. Well, taking them perhaps in reverse order, some ANDAs receive final approval without any intermediate stages. Others first receive tentative

approval and only at some later date do they receive final approval.

Q. Okay. And what is necessary for an ANDA for a generic drug to obtain tentative approval?

A. For -- it is necessary that the -- that the drug be shown in the ANDA to meet -- to meet all of FDA's regulatory requirements, which for the most part are the bioequivalence requirement and a showing of a satisfactory manufacturing process.

Q. Okay. And what's the operative effect of an ANDA having received tentative approval?

A. There is no operative effect. A tentative approval does not permit the applicant to market the drug.

Q. What's necessary for an ANDA for a generic drug to receive final approval?

A. To receive final approval, the -- all the requirements that I mentioned for tentative approval apply.

In addition, there must be no statutory barrier in terms of time to FDA's issuance of final approval; that is to say, any applicable exclusivity periods enjoyed by other manufacturers must have expired.

Q. Okay. So, if I have tentative approval for a drug, what stands between me obtaining final approval

and being able to market the drug?

A. Typically an exclusivity period.

Q. Okay. Do you have -- and would that include, among others, 180-day exclusivity under the Hatch-Waxman Act?

A. Yes, it would.

Perhaps I should add just a small footnote to that. Occasionally there might be labeling issues to be worked out on -- finally worked out with FDA, but I don't believe that typically -- that would stand between tentative and final approval, but that's not usually the case.

Q. Do you have an understanding as to what were Congress' goals or purposes in enacting the Hatch-Waxman Act?

A. Yes, I do.

Q. And briefly, what is your understanding of Congress' goals or purposes in enacting that Act?

A. Well, briefly, Congress appears to have had two separate and distinct goals or purposes in enacting the Hatch-Waxman Amendments, which are to some extent conflicting. The first was the goal of expediting the approval process and therefore the availability to the public of generic drugs.

The second goal was to -- not -- was to limit

the disincentives to innovation in the pharmaceutical industry that the availability of generic approvals might erect and also to provide some counterbalancing affirmative incentives to innovation by the brand name manufacturers.

Q. Just to briefly back up one second, what is the operational effect of an ANDA receiving final approval?

A. The operational effect is that the generic product in question can be legally marketed in the United States.

Q. Okay. Now, returning to the purposes or goals of Congress in enacting the Hatch-Waxman Act, with regard to the first purpose or goal that you mentioned in terms of facilitating generic drugs being approved and coming to market, how does the Hatch-Waxman Act further that goal?

A. It furthers it by eliminating the previous requirement that the generic manufacturer replicate the large and expensive body of safety and effectiveness data that was generated on the active ingredient by the innovator or brand name manufacturer.

Q. Does the process established by the Hatch-Waxman Act contemplate entry of generic drugs to the market prior to expiration of the patents on the corresponding pioneer or innovator drug?

A. Yes, it does.

Q. And how does it do so?

A. In two ways. First -- and we -- perhaps we will be getting into this a little bit later, but if upon filing of an ANDA for a generic drug by an applicant who is challenging the patent, the relevant patent, if the patent holder doesn't file an infringement suit within a very short period of time after that filing, FDA is free to approve the generic regardless of the existence of the patent.

More importantly, the Act contemplates that if a generic applicant does challenge the validity or applicability of a patent on the brand name drug and if the patent is subsequently held to be invalid or noninfringed by the generic, then the Act contemplates FDA approval of the generic without regard to the existence of the patent.

Q. Okay. Now, I want to ask you some questions in order for you to explain how the ANDA approval process works, basically what occurs under the Hatch-Waxman Act when a generic drug manufacturer attempts to get an approval of its ANDA and come to market with a generic drug product.

First, what role does the manufacturer of the pioneer or innovator drug have in the approval process

for generic drugs under the Hatch-Waxman Act?

A. A very -- a very limited role. The -- when an innovator or brand name manufacturer files a full NDA for an innovator/pioneer product, it must include in the NDA a list of every patent, every composition or formulation and every use patent that it believes could reasonably be said to claim the drug. That is the branded manufacturer's role.

Q. And what happens to the patent information provided to the FDA by an NDA applicant?

A. The information is compiled and published by FDA in a list that is officially titled List of Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book.

Q. And in what forms is the Orange Book made available?

A. In two forms. It's made available in an annual paperback volume that has always had a bright orange cover with monthly cumulative supplements. It is also available in electronic form online via FDA's internet web site.

Q. Okay. And what is the relevance of the Orange Book patent listings regarding the pioneer drug for a generic drug seeking FDA approval of its ANDA?

A. The generic -- when a generic manufacturer

files an ANDA for a generic version of a brand name drug, it must include in the ANDA a certification relating to the patents that have been listed for that brand name drug in the Orange Book.

Q. Okay. And please describe the certifications by an ANDA filer regarding the patents.

A. The statute provides for four possible certifications known as Paragraph I, Paragraph II, Paragraph III and Paragraph IV certifications after the subparagraphs of the statute that create them.

A Paragraph I certification is simply a certification that there are no patents listed in the Orange Book for that brand name product. A Paragraph II certification is a certification that all the patents listed have already expired. A Paragraph III certification is simply a certification of the expiration dates of unexpired patents that are listed for that innovator drug in the Orange Book. A Paragraph IV certification is a certification that in the opinion of the generic applicant, the patent on the brand name product is either invalid or not infringed or would not be infringed by the generic applicant's product.

Q. Now, do these different certifications affect when the FDA is allowed to approve an ANDA for a

generic drug?

A. Yes, they do.

Q. And how does the ANDA filer's patent certification affect when FDA may approve the ANDA?

A. If the ANDA contains a Paragraph I -- that is, no patents listed -- certification or a Paragraph II certification -- that is, all the listed patents have expired -- FDA is free to grant final approval of the ANDA as soon as all regulatory requirements have been met without any further delays.

If the certification filed was a Paragraph III certification, FDA is prohibited by the statute from approving -- from approving the ANDA until the last of the listed expiration dates has come and gone.

If a Paragraph IV certification is filed, a complicated set of rules comes into play.

Q. Okay, and please explain what happens when there is a Paragraph IV certification by an ANDA filer.

A. When an ANDA filer includes a Paragraph IV certification, the ANDA filer is required to notify both the -- that it has done so, to notify both the patent holder and the manufacturer of the brand name product who may in some cases be different companies. And again, for simplicity, I am going to just refer to notice to the -- to the brand name manufacturer from

this point on.

When the brand name manufacturer receives notice of a Paragraph IV certification, under the statute, it has a window of 45 days within which to file an infringement suit against the generic ANDA applicant. If an infringement suit is filed within the 45-day window, FDA is not permitted to approve the ANDA until one of three events has occurred; namely, the patent expires, or the -- number two, the patent is judicially determined to be invalid or noninfringed, or finally, if 30 months, two and a half years, have gone by and the litigation -- the patent litigation is still not concluded, FDA may still at that point approve -- approve the generic.

Q. Okay. Now, what happens if the patent holder or the manufacturer doesn't sue the certifying Paragraph IV ANDA filer within the 45-day period?

A. If no suit is brought within the 45-day window, FDA, as I said earlier, is legally permitted to approve the generic product, assuming all other regulatory requirements have been met. This does not preclude the patent holder or the branded manufacturer from bringing an infringement suit after 45 days, but in the -- but the generic product will have been approved and can legally be marketed subject to whatever risk of an

infringement suit the -- and damages the generic cares to run.

Q. Now, the questions you were asked to provide opinions on in this matter all relate to the so-called 180-day exclusivity provision of the Hatch-Waxman Act and its application to parties to this proceeding. Is that correct?

A. That's correct.

Q. In order to fully understand your opinions on those specific questions, I want to ask you several questions about the Hatch-Waxman Act's 180-day exclusivity provision and the evolution and interpretation and application of that provision over time.

First of all, just what is the so-called 180-day exclusivity provision, and how does it operate?

A. The Hatch-Waxman Amendments provide that the first ANDA applicant -- that is, the first generic manufacturer to file an ANDA for a particular drug -- with a Paragraph IV certification that the patent -- the relevant patent is invalid or noninfringed, the first such applicant is entitled to a period of 180 days to be free of other generic competition; that is to say, for 180 days, the first Paragraph IV filer will be the only -- the only generic on the market, because

FDA is prohibited from approving subsequent Paragraph -- subsequent ANDAs for that drug until the 180-day period has run.

Q. Okay. And how exactly does that operate?

A. The -- well, as I said, the -- when a -- once the first generic applicant to file a Paragraph IV ANDA has done so, FDA is then -- under the statute, FDA is prohibited from approving subsequent ANDAs for other generic versions of the drug until that 180-day exclusivity period has run.

Q. Okay. And what starts the running of the 180-day exclusivity period, assuming that a first ANDA filer is entitled to that?

A. The 180-day period will be triggered under the statute by the first of two possible events to occur. The first is the beginning by -- the commencement of commercial marketing of the generic product under the ANDA by the -- that first filer. That is known as the commercial marketing trigger.

The second event that can trigger the running of the 180-day period is the -- is a decision of a court holding that the relevant patent -- that is, the patent as to which there was a Paragraph IV certification -- is invalid or not infringed. That is known as the court decision trigger.

Q. Okay. Just backing up a minute for clarification, you said that the first ANDA filer is entitled to 180 days of exclusivity so that there's no other generic manufacturer -- no other generic product of the same type on the market. Is that essentially correct?

A. The first ANDA filer to include a Paragraph IV certification.

Q. Correct. That doesn't prohibit the pioneer company from licensing a generic of its product, does it?

A. It would not prohibit the pioneer company from licensing another manufacturer to produce or to distribute the innovator brand name product, perhaps under a different name, but it would, I believe, prohibit FDA from approving another -- another ANDA, regardless of the -- of whether that subsequent ANDA filer had gotten a license -- a patent license.

Q. Okay. Now, you've mentioned the commercial marketing trigger and the court decision trigger. Is that right?

A. Yes.

Q. Okay. Now, in implementing the 180-day exclusivity provision of the Hatch-Waxman Act, did the FDA at any time interpret the statute's requirements

for 180-day exclusivity?

A. Yes, it has at various times announced interpretations of that requirement.

Q. Okay.

At this time, Your Honor, we would like to put up CX 1655, which is a demonstrative exhibit, and with your permission, would Mr. Hoffman be able to stand up and to use that demonstrative to point to as he answers a series of questions?

JUDGE CHAPPELL: If you think he needs to stand up and point to it. I think I learned last week that witnesses don't need to stand up to point to a lot of these exhibits, but if it's going to assist him, he may do so.

BY MR. NARROW:

Q. Would you prefer to stand or to sit, Mr. Hoffman?

A. It's all the same to me, but I'm happy to stand.

MR. NARROW: Okay, thank you, Your Honor.

BY MR. NARROW:

Q. Now, Mr. Hoffman, perhaps you can use this time line to help illustrate the evolution of the 180-day exclusivity provision of the Hatch-Waxman Act.

Did the FDA issue any regulations implementing

the Hatch-Waxman Act's provision regarding 180-day exclusivity?

A. Yes, it did. In October of 1994, FDA adopted a broad -- a broad range of regulations relating to abbreviated NDAs or ANDAs, including provisions on 180-day exclusivity.

Q. Now, what was the substance of the FDA's regulations concerning the 180-day exclusivity?

A. Well, there were -- there were lots of aspects of the regulations, but perhaps the most important one here was the inclusion in the regulations of a prerequisite or requirement for 180-day exclusivity which came to be known as the successful defense requirement. That was a requirement that before a first Paragraph IV ANDA filer could receive 180-day exclusivity against other generic applicants, it was required first to successfully defend a patent infringement lawsuit brought against it by the brand name manufacturer.

Q. Okay. Briefly, had the FDA made any interpretations regarding the 180-day exclusivity prior to its adoption of this regulation in 1994?

A. Yes, it had.

Q. Okay. And in what form had that occurred?

A. In July 1988, FDA sent an informational or a

guidance letter to all brand name and generic manufacturers at that time presenting its interpretation of various aspects of the 180-day exclusivity provision. That letter stated FDA's view that before a first Paragraph IV ANDA filer could receive 180-day exclusivity, it first had to be sued for patent infringement by the -- by the brand name manufacturer.

The letter also indicated FDA's belief that what was required was a successful defense of that suit.

Q. Had anything -- did anything occur after FDA's issuance of that 1988 letter to raise uncertainty about the FDA's position in that letter?

A. Yes, it did.

Q. And what had occurred?

A. In 1989, the U.S. District Court for the District of Columbia held that FDA's interpretation of the statute as including a prerequisite that the first Paragraph IV ANDA filer be sued for infringement was invalid and contrary to the statute. That decision was appealed by FDA, but it became moot while the appeal was pending, and the District Court decision was vacated under judicial mootness principles.

There in addition was a -- at approximately the

same time in 1989 another District Court decision, this one in West Virginia, in which FDA's interpretation also had been challenged. In that case, the District Court held that the -- that FDA's interpretation was a reasonable one and therefore valid.

Q. Okay. And do you recall the names of those two cases?

A. Yes, the D.C. case was called Inwood Laboratories against Young. The West Virginia case was called Mylan Pharmaceuticals against -- I believe against Shalala.

Q. And what were the implications for the positions spelled out in the FDA's 1988 letter of these two court cases?

A. Well, in my opinion, the implication was that -- the validity of FDA's interpretation was highly uncertain.

Q. Okay. Now, subsequent to this case, the FDA -- these cases, the FDA adopted this regulation in 1994. Is that correct?

A. Yes, it did, notwithstanding the split decisions, if you will, of the District Courts.

Q. Okay. Now, after the FDA adopted the successful defense regulation in 1994, the regulation that concluded in the successful defense requirement,

what occurred next with regard to the FDA's implementation or application of that requirement?

A. Well, not much, if anything, happened until late 1996 and early 1997. In late 1996, another lawsuit was brought in the District of Columbia against the FDA again challenging the validity of the successful defense requirement in the regulations, and in January of 1997, the District Court here in D.C. granted an application for a preliminary injunction, enjoining FDA from approving a -- excuse me, enjoining FDA from approving a subsequent ANDA notwithstanding that the first filer of a Paragraph IV ANDA had not yet successfully defended -- defended its lawsuit. That case is known as Mova Pharmaceutical Corporation against Shalala.

Q. Okay. And what was the basis of the District Court's reasoning, that is, the Court's reasoning supporting its decision in the Mova District Court decision?

A. The reasoning was much like that of the previous judge in D.C. who had held this interpretation invalid; namely, that the statute itself provided the prerequisites for 180-day exclusivity, and FDA's effort to add another prerequisite not cited in the statute was -- was contrary to the statute and therefore --

therefore unlawful.

Q. Okay. What was the scope of the District Court's decision in Mova?

A. Well, the decision was simply the issuance of a preliminary injunction issuing the -- well, the injunction that had been sought by the plaintiff enjoining FDA from approving the particular ANDA -- I'm sorry, enjoining FDA from approving the ANDA.

JUDGE CHAPPELL: Do you need some water?

THE WITNESS: Yes, I would like some, thank you.

(Pause in the proceedings.)

BY MR. NARROW:

Q. Mr. Hoffman, just to pick up the thread again, I had just asked you what was the scope of the District Court decisions and orders, and you had answered that. What was the scope of the application of the District Court's reasoning for the Mova decision?

A. Well, the reasoning didn't depend on anything relating to the particular litigants or their -- or their procedural posture. The reasoning was that after the successful defense requirement was an effort by FDA to add a requirement to the statute that wasn't there, and it consequently was unlawful and was contrary to the statute, or I should say, specifically the Court

ruled that there was a high likelihood that the -- this being in a preliminary injunction context, that there was a high likelihood that the successful defense requirement was unlawful.

Q. What significance, if any, was there to the fact that this decision was rendered by the District Court in the District of Columbia?

A. Well, the significance was great in that FDA, being officially headquartered in the District of Columbia, is always subject to suit here, with the result that any -- any applicant, any generic applicant that was dissatisfied with a successful defense requirement could bring suit in the District of Columbia, where there were at this point two District Court decisions holding the requirement -- essentially holding the requirement invalid.

Q. Was the District Court decision in Mova reported to the public and the pharmaceutical industry?

A. Yes, it was.

Q. And how was it so reported?

A. Well, of course, it was a -- it was a public decision that was publicly available, like all court decisions. It was also written up in the trade press, specifically in a weekly newsletter called FDC Reports or The Pink Sheet, which is a widely read newsletter in

the pharmaceutical industry.

Q. Okay. Is The Pink Sheet something you normally have read and relied upon for news and information about the pharmaceutical industry in your practice?

A. Yes, it is.

Q. And do you know who generally reads or sees The Pink Sheet?

A. In my experience, The Pink Sheet is read by a wide range of pharmaceutical company executives, managers, regulatory affairs personnel, lawyers in the legal department and lawyers in private practice who practice in this area.

Q. Could we bring up CX 600, please.

Your Honor, I apologize for the quality of some of the scanned-in documents. It may prove to actually be easier to look at the hard copies in some instances, but we will try to do both and see what works.

With regard to CX 600, Mr. Hoffman, do you recognize it?

A. Yes, I do.

Q. And what is it?

A. This appears to be a copy of the cover page and a continuation page of the -- of an issue of The Pink Sheet, the January 20th, 1997 issue, that included the story reporting the District Court decision in Mova.

Q. Could you please point out where in CX 600 it reports the Mova District Court decision concerning the successful defense requirement?

A. Really the second -- the group of paragraphs on the -- on the continuation page going on for several paragraphs. Specifically, the last sentence of the third paragraph that specifically describes it.

Yes, specifically the last sentence of the third paragraph that states in one sentence FDA's interpretation and then in another sentence the judge's ruling holding that the statute does not require successful defense as FDA had interpreted the statute.

Q. Mr. Hoffman, I'm having a little trouble determining which paragraph is which paragraph. This is a bolded indented one. Is that the fourth paragraph or the third paragraph?

A. I'm sorry, I said the third. It appears to be the fourth paragraph.

Q. Okay.

Your Honor, at this time I'd move the admission of CX 600.

JUDGE CHAPPELL: Any objection?

MR. GIDLEY: No objection, Your Honor.

MR. NIELDS: No objection, Your Honor.

JUDGE CHAPPELL: CX 600 is admitted.

(Commission Exhibit Number 600 was admitted into evidence.)

MR. NARROW: Thank you, Your Honor.

BY MR. NARROW:

Q. Mr. Hoffman, returning to the Mova case, what position did the FDA take on the issuance of the Mova case in the District Court and on appeal, frankly?

A. Well, in the District Court, FDA, of course, vigorously argued that its regulation -- that its successful defense requirement was valid. It did not appeal from the grant of the preliminary injunction. Instead, it pressed on, moving for summary judgment in the District Court.

The losing private party did appeal from the grant of the preliminary injunction. In the Court of Appeals, FDA had itself re-aligned as an appellant and continued to defend the validity of the regulation.

Q. Okay. Now, while the appeal of the Mova District Court decision was pending, what public position, if any, did the FDA announce regarding future application of the successful defense requirement?

A. A couple of months later, FDA's associate chief counsel for drugs, who was the agency's chief legal adviser on these issues, appeared at a public educational conference, actually an FDLI conference,

and announced that although FDA continued to disagree with the Mova District Court decision, it would, pending the outcome of the appeal in Mova, it would acquiesce in the Mova decision.

Q. Do you have an understanding of what the FDA meant when it said that it was going to acquiesce in the Mova decision?

A. Well, I have an understanding of what the concept of agency acquiescence is, and so far as I can tell, that's what FDA was -- the associate chief counsel for drugs was using the term in that sense.

Q. And what is your understanding of acquiescence?

A. My understanding of acquiescence is that when an administrative agency loses a case in a lower court, it may choose to abide by that decision and follow -- and follow that decision in other cases, even though it may not -- at least for a period of time, even though it may not be legally bound to do so in the sense that a particular District Court precedent may not be binding in other districts. That's what I understood the associate chief counsel for drugs to mean.

Q. Okay. And I believe you said she said that FDA was acquiescing pending appeal?

A. Yes, she did.

Q. Why did the FDA acquiesce in the Mova District

Court decision?

A. Well, as the --

MR. GIDLEY: Objection, Your Honor, foundation.

BY MR. NARROW:

Q. Do you have an understanding as to why the -- I'm sorry, Your Honor.

JUDGE CHAPPELL: We have an objection. We need to have a ruling. I expect that from the witness, but not from the attorney.

MR. NARROW: I apologize.

JUDGE CHAPPELL: Can you repeat your objection?

MR. GIDLEY: Yes, Your Honor. I object on the basis of foundation. The witness has not testified previously that he is in a position to testify as to the intent of the Food and Drug Administration at this particular point in time.

JUDGE CHAPPELL: Response?

MR. NARROW: I have none -- I have no response at this point, Your Honor. I will lay a foundation if permitted to proceed.

JUDGE CHAPPELL: Objection sustained.

BY MR. NARROW:

Q. Do you have an understanding as to why the FDA acquiesced in the Mova decision?

A. I know what FDA subsequently said about its

reasoning.

Q. Okay. And what did FDA subsequently say about its reason for acquiescing in the Mova District Court decision?

A. It subsequently said that it was acquiescing in Mova pending appeal because of the fact that I mentioned a little while ago; namely, it would be subject it suit by anyone else who cared to come to the District of Columbia and get a similar order, and therefore, for simplicity and to minimize confusion, it would -- it would acquiesce pending appeal.

MR. GIDLEY: Objection, Your Honor, and move to strike. I still haven't heard a foundation for this witness to be able to testify about what the FDA believed in May of 1997.

JUDGE CHAPPELL: Well, the question was what did the FDA say, and the witness responded with what he thought the FDA said, and on that basis, I'm overruling the objection.

You may proceed.

MR. NARROW: Thank you.

BY MR. NARROW:

Q. Was the FDA's statement of its acquiescence in the Mova District Court decision reported or made known to the pharmaceutical industry and the public?

A. Yes, it was.

Q. And how was the FDA's acquiescence in the Mova District Court decision reported or made known to the public and the pharmaceutical industry?

A. Well, first, of course, it was immediately known to industry representatives who were at the FDLI conference where the associate chief counsel made the statement. Subsequently, her remarks were reported or described in an article in the -- in The Pink Sheet, the weekly pharmaceutical industry newsletter that I mentioned earlier.

JUDGE CHAPPELL: The witness needs to return to the witness stand, please. He's standing in front of a blank screen.

MR. NARROW: Okay, I'm sorry.

JUDGE CHAPPELL: Thank you.

BY MR. NARROW:

Q. Bring up CX 636, please.

Mr. Hoffman, do you recognize CX 636?

A. Yes, I do.

Q. And what is it?

A. This appears to be a copy of another issue of The Pink Sheet, this one from May 26, 1997, and a continuation page containing the report of, among other things, the report of the associate chief counsel's

speech.

Q. Okay. Could you identify where in CX 636 FDA's announcement of its acquiescence in the Mova District Court decision was reported?

A. Yes, it's -- her remarks are described in the last two paragraphs, and particularly in the last paragraph where she is quoted in the first line of the last paragraph as saying, "Right now, we are acquiescing to the Mova court decision," and then she goes on on a related issue. That's the one.

MR. NARROW: I don't know how legible that is, Your Honor.

JUDGE CHAPPELL: Excuse me?

MR. NARROW: I don't know if that's sufficiently legible on your screen or not.

JUDGE CHAPPELL: It's fine. I don't think we need him to go over there and point to a paragraph. I think he can do that from the witness stand.

MR. NARROW: Okay, thank you, Your Honor.

At this point I'd like to move the admission of CX 636 into evidence, Your Honor.

JUDGE CHAPPELL: Any objection?

MR. NIELDS: No objection, Your Honor.

MR. GIDLEY: No objection, Your Honor, provided it's not being offered for the truth of the matter

asserted, simply that these words appeared in The Pink Sheet.

MR. NARROW: Yes, Your Honor, that's the purpose for which it's being offered.

JUDGE CHAPPELL: What is that number, 636?

MR. NARROW: 636, Your Honor.

JUDGE CHAPPELL: CX 636 is admitted.

MR. NARROW: Thank you, Your Honor.

(Commission Exhibit Number 636 was admitted into evidence.)

BY MR. NARROW:

Q. Now, after the FDA stated that it was going to acquiesce in the Mova District Court decision, was there any subsequent confirmation of the FDA's acquiescence in not enforcing the successful defense requirement for 180-day exclusivity?

A. Yes, there was.

Q. And what subsequent confirmation of FDA's acquiescence in Mova occurred?

A. Less than a month later, FDA sent substantially identical letters to all the pending generic ANDA applicants for generic forms of a drug called Zantac. The generic name is ranitidine, but ranitidine is the generic name for Zantac. FDA sent letters to all the generic Zantac applicants stating that it was

acquiescing in the Mova decision and acting -- and announcing an action based on that acquiescence.

Q. And what was the status of the Mova appeal at this time?

A. It was pending in the Court of Appeals.

Q. Okay. Now, exactly how did the FDA apply the Mova District Court decision to this instance?

A. FDA announced that it was granting -- it was granting 180-day exclusivity to the generic applicant that it deemed to be the first to have filed a Paragraph IV certification on the -- on the relevant patent, even though that first Paragraph IV filer had not successfully defended against an infringement suit.

Q. Okay. And who was it that was awarded 180-day exclusivity?

A. A company called Genpharm, G E N P H A R M.

Q. Okay. And had there been patent infringement litigation regarding generic Zantac and involving Genpharm?

A. Yes, there had.

Q. And what had occurred in that litigation?

A. Genpharm had filed a Paragraph IV certification with respect to the relevant patent, had been sued by the brand name manufacturer, and after a period of litigation in the District Court settled the case by

agreeing to a consent judgment containing an express finding that the patent in question was valid and would be infringed by the -- by the Genpharm product.

Q. And how do you know that the FDA determined that Genpharm was entitled to 180-day exclusivity?

A. Because it -- it said so in the letters to the -- to the various generic Zantac applicants.

Q. Okay. And how do you know that Genpharm had settled its patent litigation with the court entering the final judgment that included the finding that the patents at issue were valid and had been infringed by Genpharm?

A. FDA so stated in the letter to Genpharm informing it that it had been awarded 180-day exclusivity.

Q. Could you please pull up CX 602, which, Your Honor, previously has been admitted into evidence.

Mr. Hoffman, do you recognize CX 602?

A. Yes, I do.

Q. And what is it?

A. That's the letter to Genpharm or, strictly speaking, to Genpharm's U.S. agent that I described a minute ago.

Q. Okay. Please identify where in the letter it discusses the granting of 180-day exclusivity to

Genpharm based on the FDA's acquiescence in the Mova District Court decision.

A. In the last paragraph on the first page of the letter, starting in the -- starting in the -- really I guess in the end of the third line, going on to cite the patent infringement actions that had been brought and then stating in the last three lines of the paragraph that the litigation ended in a final judgment on consent finding the patents -- the listed patents valid, enforceable and infringed.

Q. Could we now pull up CX 595, which also has previously been admitted into evidence, Your Honor.

Do you recognize CX 595?

A. Yes, I do.

Q. And what is it?

A. This is -- appears to be a copy of the letter that -- the identical letter that FDA sent to each of the other generic Zantac applicants. For some reason, the name and address of the particular recipient of this one was whited out. This was the letter informing the other applicants of what had been done regarding Genpharm.

Q. And where does this document, CX 595, mention Genpharm's 180-day exclusivity?

A. In the carryover from the last sentence on page

1 to the top of page 2 of the letter.

Q. Now, regarding CX 595, do you know to whom this letter was sent?

A. Yes, I do.

Q. And to whom was it sent?

A. You mean the names of the companies?

Q. Yes, if you know them.

A. I believe it was sent to Geneva Pharmaceuticals, Novopharm or at least to a subsidiary of Novopharm, to a company called Boehringer Ingelheim, and perhaps -- and a company called Torpharm, T O R P H A R M, and possibly Mylan Pharmaceuticals as well.

Q. And how do you know that the letter identified as CX 595 was sent to those firms?

A. Well, I learned that pretty quickly after they were sent, because I was then advising a -- one of the companies involved that it had received the letter. The -- the letter and its addressees was also reported in yet another issue of The Pink Sheet.

Q. Okay. Could we call up CX 605 at this time, please.

Do you recognize CX 605?

A. Yes, I do.

Q. And what is CX 605?

A. It appears to be a copy of the cover page and a

continuation page of The Pink Sheet issue of June 23rd, 1997 describing FDA's letters to the generic Zantac applicants and stating to whom they had been sent.

Q. Could you please point out where in CX 605 it identifies the ANDA filers other than Genpharm?

A. I believe it's on the second continuation page, the bold-faced paragraph about halfway down the page, I guess it's the fifth new paragraph.

Q. And now, is it your understanding that those were the ANDA filers who received copies of CX 595?

A. Yeah, that is my understanding.

MR. NARROW: At this time I would move the admission of CX 605, Your Honor.

JUDGE CHAPPELL: Objection?

MR. GIDLEY: Again, Your Honor, we would object if it's actually being offered for the truth of the matter asserted. As long as it's being offered simply to provide the basis of what appeared in The Pink Sheet on that date, we would not have an objection to that extent, Your Honor.

MR. NARROW: It's being --

MR. NIELDS: Same position, Your Honor.

MR. NARROW: It's being offered for notice and information, not necessarily for the truth of the contents, Your Honor.

JUDGE CHAPPELL: Okay, with that understanding -- what's the exhibit number?

MR. NARROW: 605.

JUDGE CHAPPELL: CX 605 is admitted.

MR. NARROW: Thank you, Your Honor.

(Commission Exhibit Number 605 was admitted into evidence.)

BY MR. NARROW:

Q. Now, was the FDA's action in granting the 180-day exclusivity to Genpharm as to generic Zantac, again, a first Paragraph IV ANDA filer that had not successfully defended its patent infringement action, was that action made public?

A. Yes, it was.

Q. And when and how was FDA's action granting Genpharm 180-day exclusivity made public?

A. Well, I suppose it was first made public via the filing of a lawsuit in the U.S. District Court for the Eastern District of North Carolina by one of the applicants who did not get exclusivity. The -- that event was also reported in the Wall Street Journal and, of course, in The Pink Sheet story that has just been shown.

Q. And when was that case filed by this affected ANDA filer you mentioned?

A. It was filed before the end of the same day in which the letters were transmitted to the -- to the applicants, June 17th, 1997.

Q. Okay. Returning to CX 605 again, which we were just previously discussing and was admitted into evidence, could you identify where that exhibit discusses FDA's awarding the 180-day exclusivity to a first ANDA filer that had not successfully defended in its patent infringement litigation?

A. Yes, the -- the three paragraphs at the end of the second continuation page, beginning, "FDA's decision on ranitidine exclusivity is in part based on the Mova ruling," and then going on from there.

Q. Okay. Following the FDA's action on the generic Zantac ANDAs, in the summer of 1997, was there litigation relating to the FDA's successful defense requirement?

A. Well, whether it was summer or not, on June 17th, the same day that the first of the letters was transmitted, litigation was begun in the Eastern District of North Carolina by one of the -- one of the applicants that had not received exclusivity; namely, Granutec, which was actually a subsidiary of Novopharm to whom the -- I believe the letter was addressed.

Q. And was that the same court case that you

referred to earlier?

A. Yes.

Q. Now, what was the FDA's position in this litigation?

A. Well, the FDA's position in this litigation was fairly complicated. On the one hand, FDA argued that its acquiescence in the Mova decision pending appeal was a reasonable exercise of its administrative discretion. On the other hand, it simultaneously argued that the successful defense regulation that it had declined to follow was valid. So, FDA was actually arguing in support of both parties, if you will.

Q. What was the District Court's decision in this case?

A. The District Court very promptly decided that the regulation was valid and binding and issued a permanent injunction requiring FDA -- requiring FDA to approve the plaintiff Granutec's ANDA on the ground that the -- that Genpharm, the first filer, had not met the requirement of the regulation.

Q. Is this case what is known as the Granutec decision?

A. This is the Granutec decision, yes, sir.

Q. What order did the District Court enter there?

A. It entered an order requiring FDA to approve

Granutec's, the plaintiff's, ANDA.

Q. Now, what happened after the District Court's decision in Granutec?

A. All the losing parties appealed to the Court of Appeals for the Fourth Circuit, which granted a stay of the District Court order subject to the filing of an appeal bond in the amount of $10 million, which was done.

Q. Okay. Were the Granutec District Court decision and the subsequent stay pending appeal publicly reported?

A. Yes, they were.

Q. Where and how were the Granutec District Court decision and subsequent stay reported?

A. Well, again, The Pink Sheet reported first the District Court decision and then the subsequent issue reported the stay. The Wall Street Journal also reported both developments as they occurred.

Q. Okay. Now, what action, if any, did the FDA take following the stay of the Granutec District Court decision?

A. While the appeal was pending and while the stay was in force, FDA announced in November of 1997 that it was terminating its acquiescence in the Mova -- in the Mova decision pending the outcome of the Mova appeal

and would resume applying and enforcing the successful defense requirement in the statute.

Q. Now, at this time --

A. I'm sorry, in the regulation.

Q. I'm sorry. Now, at this time were the appeals in both Mova and Granutec pending?

A. Yes, they were.

Q. And what happened in the appeals of Mova and Granutec in those cases?

A. In April of '98, both appeals were decided. First, on April 3rd, 1998, the Fourth Circuit -- the Fourth Circuit overruled the -- or reversed the District Court decision in Granutec and held that the successful defense requirement in FDA's regulation was invalid as contrary to the statute.

Eleven days later, on April 14th, the D.C. Circuit issued a substantially similar ruling, also holding the successful defense regulation invalid as contrary to the statutes.

Q. And what happened on the remand of the Mova case?

A. The -- on remand, the District Court granted the Government's -- I'm sorry, granted the plaintiff's summary judgment motion and entered a permanent injunction specifically enjoining FDA from applying or

enforcing the successful defense regulation generally.

Q. And what did the FDA do in response to the Court of Appeals' decision and the permanent injunction that were issued on the remanded Mova case?

A. In November of '98, FDA amended the ANDA regulations to remove the successful defense provisions.

Q. Now, we've covered a lot of background information regarding the evolution of the FDA's successful defense requirement for entitlement to 180-day exclusivity under the Hatch-Waxman Act, and I'd like to turn now to the specific questions relating to 180-day exclusivity and the successful defense requirement that you were asked to address by complaint counsel and obtain your answers and have you explain your answers in light of this history that we have just discussed.

First, have you considered the question of whether on June 17th, 1997, the date of the Schering/Upsher-Smith settlement agreement, there was substantial uncertainty whether Upsher-Smith, as the first to submit an abbreviated new drug application containing a Paragraph IV certification, under 21 USC Section 355(j)(2)(A)(vii)(IV) for 20 milliequivalent extended release potassium chloride tablets would be

entitled to a 180-day exclusivity period under 21 USC Section 355(j)(5)(B)(iv) for that drug if it settled the patent infringement suit brought against it by Schering without a judicial determination that the patent in suit was invalid or not infringed?

A. Yes.

Q. And that's a mouthful, and I am not going to repeat that each time in an attempt to shorten that question, but in each instance, my question to you as to your opinion relates to that full question.

A. I understand.

Q. Are you prepared today to offer your opinion on that question as to whether on June 17 there was substantial uncertainty about Upsher's entitlement to 180-day exclusivity?

A. Yes.

Q. And what is your opinion on that question as to whether on June 17th there was substantial uncertainty about Upsher-Smith's entitlement to 180-day exclusivity?

A. My -- if it were to settle the case without --

Q. If it -- yes, if it had settled its patent infringement suit, again, without a final judicial determination that the patent in suit was invalid or noninfringed.

A. My opinion is that on June 17th, 1997, there was substantial uncertainty on that question.

Q. Okay. Now, what's the basis for your conclusion that there was substantial uncertainty about Upsher-Smith's entitlement to 180-day exclusivity on June 17th, 1997?

A. Well, at that point in time, there were considerations or factors pointing in opposite directions as to whether Upsher would or wouldn't be entitled to exclusivity.

Q. Okay. And what information or factors would support the conclusion that Upsher would be entitled to 180-day exclusivity as of June 17 if it settled its case with Schering without a court finding of patent invalidity or infringement?

A. Well, at that point, two separate judges in the U.S. District Court for D.C. had held that the requirement -- the successful defense requirement was either invalid or highly likely to be invalid and contrary to the statute.

MR. NIELDS: What is the basis for that, if I may ask, Your Honor? He's testified about two cases, one of which involved the successful defense requirement and the other of which involved something about whether the first filer had to be sued.

MR. GIDLEY: Same objection, Your Honor. Excuse me.

JUDGE CHAPPELL: That was an objection? Tell me again the legal basis for your objection.

MR. NIELDS: No foundation, Your Honor.

MR. NARROW: I believe the references to the Inwood case --

THE WITNESS: I'd be happy to explain if that would clarify things.

MR. NARROW: No, I believe he testified that at issue in the Inwood case was the FDA's position in its 1988 letter, which included both the requirement to be sued and that there be successful defense mentioned in that letter.

JUDGE CHAPPELL: Okay, the question was, more or less, what information or factors support a conclusion. The question before that was what's the basis for a conclusion about uncertainty in the 180-day period.

Would you read that question back, Susanne?

(The record was read as follows:)

"QUESTION: And what information or factors would support the conclusion that Upsher would be entitled to 180-day exclusivity as of June 17 if it settled its case with Schering without a court finding

of patent invalidity or infringement?"

JUDGE CHAPPELL: Based on that question, it requires its own foundation. Accordingly, the objection is overruled. You may answer the question.

THE WITNESS: Well, starting the answer again, which may or may not come out in the same precise words, at that point in time, there were two court decisions in the U.S. District Court for D.C., the Inwood decision in 1989 and the Mova decision in 1997, the Inwood decision holding that the requirement -- any requirement that the first filer be sued at all was invalid, and the Mova decision specifically addressing the successful defense requirement, holding that that requirement was invalid as contrary to the statute.

In my opinion, the Inwood decision is a factor pointing in that -- in the particular direction because if there's no requirement that the party be sued, the fact that the suit hasn't concluded with a successful defense seems to be irrelevant a fortiori.

JUDGE CHAPPELL: Mr. Narrow, we have been going almost three hours, so let me know when you are at a breaking point.

MR. NARROW: I'm sorry, I thought we started at about 2:30, Your Honor.

MR. NIELDS: He's talking about the rest of us.

JUDGE CHAPPELL: Some of us have not had a break, Mr. Narrow.

MR. NARROW: I'm sorry.

JUDGE CHAPPELL: So, when you finish this line of questioning, let me know.

MR. NARROW: I think if it's acceptable to Your Honor, in about a minute or two when I finish this line of questioning, a couple of minutes, it would be an appropriate time for a break from my standpoint, but whatever you would prefer obviously is --

JUDGE CHAPPELL: That will be fine. You may proceed.

MR. NARROW: Thank you.

BY MR. NARROW:

Q. Okay, now, the question I had asked was what factors or information would support the conclusion that Upsher would be entitled to exclusivity as of June 17th, 1997 if it settled its case without a court finding of patent invalidity or noninfringement, and you mentioned the Inwood and Mova District Court decisions, correct?

A. Correct.

Q. Were there any other factors that would suggest that Upsher would be entitled to exclusivity as of that date if it settled?

A. Well, FDA had also in May announced its intention to acquiesce in the Mova decision pending appeal, meaning that it would -- meaning to me that it would apply the Mova ruling in subsequent cases that came before it in deciding whether to grant exclusivity, to the extent they came before it while the appeal in Mova was still pending.

Q. And did the FDA, in fact, apply that position?

A. Yes, it did, on -- on June 17th and 18th, in the letters to the generic Zantac applicants.

Q. Now, given -- okay. What factors or information would support the conclusion that Upsher might not be entitled to 180-day exclusivity as of June 17th, 1997 if it settled its case with Schering without a court finding of patent invalidity or noninfringement?

A. Well, foremost, of course, the -- was the successful defense regulation itself, which was still on -- still on the books as a regulation, and to that, I suppose one might add the 1989 -- the old 1989 Mylan decision, which speaking of the requirement that a -- the predicate requirement that the first filer be sued in order to get exclusivity, holding that that was a valid interpretation of the statute.

So, we had District Court decisions going both

ways, a regulation in force which FDA announced it was not going to apply during the pendency of the appeal.

Q. Now, given that the Mova District Court decision didn't involve a Paragraph IV -- a first Paragraph IV ANDA filer that had settled its litigation, why would that decision apply to Upsher if it did settle its litigation with Schering?

A. Well, as a matter of -- first of all, as a matter of logic, if there's no requirement that there be a successful defense or even a requirement that there be a lawsuit, the fact that there was a lawsuit which was settled without a -- without a decision on the patent either way seems to me to be logically relevant.

In addition, on June 17th, that very day, FDA implemented its acquiescence policy and actually granted exclusivity to a first Paragraph IV ANDA filer who had settled the litigation, and indeed, settled with a -- by consenting to a judgment that the patent was, in fact, valid and was, in fact, infringed.

Q. And what party was that that had settled?

A. That was Granutec -- I'm sorry, that was Genpharm.

Q. And was that -- was Genpharm's settlement what we had mentioned earlier when we were looking at the

letters to Genpharm and to the other ANDA filers concerning Zantac -- a generic Zantac?

A. That is my understanding, yes.

MR. NARROW: Your Honor, this would be a good time to take a break if that's convenient for you.

JUDGE CHAPPELL: Okay, let's take a recess until 4:35.

(A brief recess was taken.)

JUDGE CHAPPELL: You may continue, Mr. Narrow.

MR. NARROW: Thank you, Your Honor.

BY MR. NARROW:

Q. Now, Mr. Hoffman, I would like to move on to the second question you were asked to address by complaint counsel that relates to 180-day exclusivity and the successful defense requirement and again have you explain your answer in light of the history that you've provided.

Have you considered the question of whether on January 23rd, 1998, the date of the Schering-ESI agreement in principle, there was substantial uncertainty whether Upsher, having settled Schering's patent infringement suit without a judicial determination that the patent in suit was invalid or not infringed, was entitled to 180-day exclusivity?

A. Yes.

Q. Now, are you prepared today to offer your opinion as to whether on January 23rd, 1998, there was substantial uncertainty about whether Upsher was entitled to 180-day exclusivity on that date?

A. I am.

Q. Okay. And what is your opinion regarding the question of whether on January 23rd, 1998, Upsher, having settled Schering's patent infringement suit without a judicial determination that the patent in suit was invalid or not infringed, was entitled to 180-day exclusivity?

A. The uncertainty in my opinion was equal or greater to that on June 17th, '97.

Q. What is the basis for your concluding that on January 23rd, 1998, Upsher's entitlement to exclusivity was equally or more uncertain than it had been on June 17th, 1997?

A. Well, all the factors in play on June 17th were still -- were still operative. In addition, there had been a number of subsequent developments that simply compounded the uncertainty; namely, the District Court in the Granutec litigation in North Carolina had held that the regulation was valid and ordered FDA in that case to comply with it, setting up a square conflict with the District Court in the Mova case in D.C.

FDA had changed its position again -- yet again and had terminated its temporary acquiescence policy and announced that it would henceforth apply the regulation as written.

MR. NARROW: At this time, Your Honor, I would move the admission of CX 1655.

JUDGE CHAPPELL: Any objection?

MR. NARROW: That's the demonstrative.

MR. NIELDS: You have just switched the demonstrative. If you could go back to what you are offering, it would help.

MR. NARROW: Yes, I'm sorry. Would you go back to 1655, the previous document? Thank you.

MR. NIELDS: Your Honor, I'm sure I'm going to have no objection to this, but it seems to me that the basis for this hasn't been completed yet. There are some events in this chart that have not been testified about by the witness.

MR. GIDLEY: Your Honor, we would object on the basis of completeness. We would also note, Your Honor, that in terms of demonstratives in general, the idea of admitting a demonstrative time line seems to us to be kind of an odd concept. If the witness testifies to events, his testimony is what it is, and if they want to summarize that for the assistance of the Court in a

demonstrative, fine, I'm sure we'll do the same thing, but to actually admit the demonstrative, I'm not sure we even understand for what purpose, independent from his testimony, the demonstrative would be offered, Your Honor.

JUDGE CHAPPELL: Mr. Narrow, you did refer to this as a demonstrative. Is that right?

MR. NARROW: That's correct, Your Honor.

JUDGE CHAPPELL: Are you offering it as evidence or is it merely a demonstrative exhibit? If it is, then you should offer it for identification purposes. It's your choice. You may take a moment to confer if you need to.

MR. NARROW: If I may.

(Counsel conferring.)

MR. NARROW: Your Honor, we would just move its admission for identification purposes to demonstrate what the witness was referring to in his testimony.

MR. NIELDS: I have no objection to that, Your Honor.

MR. GIDLEY: So limited, we have no objection, Your Honor.

MR. NARROW: Thank you, Your Honor.

JUDGE CHAPPELL: And with that qualification, it's admitted. That would be CX --

MR. NARROW: 1655.

JUDGE CHAPPELL: -- CX 1655. Thank you.

(Commission Exhibit Number 1655 was admitted into evidence.)

JUDGE CHAPPELL: You may proceed.

MR. NARROW: Thank you.

BY MR. NARROW:

Q. If we could put up the second demonstrative, CX 1656. Thank you.

Now, earlier, Mr. Hoffman, I believe you testified that the Hatch-Waxman Act contained two triggers that could start the running of the 180-day exclusivity period of a first Paragraph IV ANDA filer, the first commercial marketing trigger and the court decision trigger. Is that correct?

A. Correct.

Q. Now, I would like to turn to the trigger of the court decision trigger. Again, using this demonstrative exhibit, would you please describe the interpretation and the operation of the court decision trigger beginning from the Hatch-Waxman Act enactment in 1984 up until June 17th, 1997.

A. Well, for a period of time after 1984 when Hatch-Waxman was enacted, there was no particular attention paid to the wording or significance of the

court decision trigger. In the July 1988 guidance letter, which I'm afraid is shown here as -- on the demonstrative as November, but it was July, if I recall, FDA's description of its then -- its views at that time on the 180-day exclusivity provision seemed to assume, if you read the wording of the letter, there is just to me an apparent assumption that the -- that the court decision that triggers the 180-day exclusivity period is a decision in the patent infringement case against the first ANDA filer, which -- which was brought in response to the Paragraph IV -- Paragraph IV notice.

In the ANDA regulations that were issued in 1994, once again, the provisions dealing with 180-day exclusivity are worded in such a way as to suggest that FDA continued to assume that the triggering decision that Congress had in mind was the -- would be the decision in the infringement suit brought against the Paragraph IV -- first Paragraph IV filer.

My recollection of -- personal recollection of the -- of the period is that it was commonly if not universally assumed at that time among lawyers practicing in this field and the industry that that's what the provision -- that's what the provision meant.

In fact, as late as March 19 -- February or

March 1997, a new and different theory of how the statute might be interpreted was advanced in a petition to FDA by a private law firm on behalf of -- apparently on behalf of an unnamed client seeking a change in the regulations to accommodate the new theory, and again reflecting, I believe, in that case specifically, explicitly, the understanding that the regulations as they then stood required that the court decision -- that the only court decision that could trigger the period was that in the patent infringement suit against the first Paragraph IV filer whose exclusivity was at issue.

Q. Had any courts addressed the court decision trigger?

A. Up to -- up to that point, to my knowledge, no court had addressed the question of the court decision trigger at all or at least not in the sense of whether -- whether a -- whether it was only the decision in the first Paragraph IV filer's case that could operate as a trigger.

Q. Now, you mentioned that there was a citizen's petition, I believe, that was filed in March of 1997. Is that correct?

A. That's correct.

Q. Okay. And what was that -- the status of that

petition prior to June 17th, 1997?

A. Well, a citizen's petition is just FDA -- or citizen petition is just FDA's term for a petition to the agency asking it to take some action. The -- that was a petition, as I said, filed by a private law firm on behalf of one assumes a private client. It had been filed -- it had been submitted to FDA, placed on the docket of submitted petitions, but other than that, nothing -- nothing had been done.

For example, FDA's regulations provide that in cases FDA deems appropriate, it may publish notice of the filing of the citizen petition and solicit public comments on the petition. FDA did not do so in this case. The petition simply was filed and sat there.

Q. Okay. What importance, if any, did filing this petition have regarding the FDA's interpretation of the court decision trigger?

A. I don't believe it had any importance whatsoever. It was simply an argument being put forward by a private law firm, and people ask FDA to do things, take positions all the time.

Q. Now, what happened on June 17th, 1997 regarding the FDA's interpretation of the court decision trigger for 180-day exclusivity?

A. Well, that was the date -- June 17th and 18th

were the dates of the FDA's letters to the generic Zantac applicants, which announced that exclusivity had been awarded to Genpharm even though Genpharm had not -- had not successfully defended a patent infringement suit and, in fact, even though it had settled its own patent infringement suit and settled with a finding of -- express finding of patent validity and infringement.

The second component of the letters was the ruling that -- or the announcement of FDA's decision that Genpharm's exclusivity period had already been triggered some months earlier by a decision in an entirely unrelated piece of litigation against -- by the brand name manufacturer against one of the other applicants in which the Court had made a determination that the relevant patent was -- was invalid or noninfringed, I'm not sure which.

Q. Okay. Now, you mentioned that this new position by the FDA was included in the generic Zantac letters that we had discussed previously?

A. Yes, it was.

Q. Okay. And those were identified as CX 602 and CX 595. Is that correct?

A. Well, I can look in my -- in my volume -- in my binder. Yes, that's the case.

Q. Okay. Would you look at CX 602, please, and -- which previously has been admitted, and point out where in that letter the FDA announces that it is applying new interpretation of the court decision trigger for 180-day exclusivity.

A. On the second page of the letter, the letter begins to discuss the topic in the -- about the middle of the page. In the second new paragraph, it recites the statute and then says in the -- the first sentence of the last paragraph, "The agency interprets this provision as triggering the beginning -- this provision as triggering the beginning of the 180 day exclusivity period with a decision of any court," underscored, "in a patent infringement action related to a paragraph IV certification, whether or not it is the court hearing a patent infringement action resulting from the first paragraph IV certification."

Then it goes on to identify the court decision that it deemed to have triggered Genpharm's exclusivity in the particular case. It goes on on page 3.

Q. Thank you.

Now, will you take a look at CX 595, please, and point out where in that letter the FDA announces that it is applying a new interpretation of the court decision trigger for 180-day exclusivity?

A. The top half or so of page 2 of that letter, which is substantially identical to the provision I just more or less read from in the first exhibit.

Q. Okay, thank you.

Now, was the FDA's new interpretation of the court decision trigger made known to the public and the pharmaceutical industry?

A. Yes, it was.

Q. And how was it made known to the public and the pharmaceutical industry?

A. It was described in the weekly Pink Sheet newsletter story that I identified earlier.

Q. Okay. Would you please turn back to CX 605, which previously was admitted into evidence.

A. I have it.

Q. Is that The Pink Sheet article that you were referring to?

A. Yes, it is.

Q. Okay. Would you please indicate where in CX 605 the article refers to the FDA's new interpretation regarding the court decision trigger?

A. Yes, I believe it's at the -- about two-thirds of the way down the second page, and it goes on most notably, really quoting from the FDA letters, in the last paragraph at the bottom of the second page.

Q. Thank you.

Now, after the FDA's issuance of the generic Zantac letters on June 17th and 18th, 1997, what was the response to the FDA's position that a court decision in a later Paragraph IV ANDA filer's patent infringement suit could trigger a first filer's 180-day exclusivity?

A. Well, naturally, that was vigorously contested by I think just about every one of the numerous litigants participating in the -- in the Granutec litigation in which FDA's decision had been challenged. FDA defended its interpretation, and various parties argued that it was incorrect.

Q. Was this the same Granutec litigation that we discussed before in which the FDA's successful defense regulation ultimately was held to be unlawful by the Court of Appeals?

A. Yes. Yes, it was.

Q. Okay. Now, again, we've covered a fair bit of background information regarding the court decision trigger for 180-day exclusivity under the Hatch-Waxman Act. I'd like to turn now to the specific questions that you were asked to address by complaint counsel and that relate to that court decision trigger and have you explain your answers in light of the history that

you've provided.

Have you considered the questions of whether on June 17th, 1997 and on January 23rd, 1998, respectively, there was a substantial possibility that a judicial determination of patent invalidity or noninfringement in Schering's patent infringement suit against ESI Lederle with respect to the same product we've been discussing before would trigger any 180-day exclusivity period to which Upsher was entitled on that product?

A. Yes.

Q. And are you prepared today to offer your opinion on that question?

A. I am.

Q. And what is your opinion as to whether on June 17th, 1997 -- well, first let's do this one date at a time.

What is your opinion as to whether on June 17th, 1997 there was a substantial possibility that a judicial determination of patent invalidity or noninfringement in Schering's patent infringement suit against ESI Lederle with respect, again, to the 20 milliequivalent product would trigger any 180-day exclusivity period to which Upsher was entitled?

A. In my opinion, at that time, there was no

substantial reason to believe that a decision in what I hope you'll let me call third-party litigation could trigger -- could have triggered Upsher's exclusivity.

Q. Okay. And what is your opinion as to whether on January 23rd, 1998, the date of the Schering-ESI agreement in principle, there was a substantial possibility that a judicial determination of patent invalidity or noninfringement in Schering's patent infringement suit against ESI Lederle with respect to the 20 milliequivalent product would trigger any 180-day exclusivity to which Upsher was entitled?

A. By that time, there was a -- in my opinion, there was a substantial possibility that a third-party decision such as one in the suit against ESI Lederle would be held to trigger Upsher's exclusivity.

Q. Okay. What's the basis for your conclusion that as of June 17th, 1997, there was no substantial reason to believe that a judicial determination in the Schering-ESI litigation would trigger any exclusivity that Upsher would have?

A. Well, at -- as of June 17th, 1997, it was -- at that point, it had not been seriously suggested or suggested in any other nonserious way, except by this one citizen's petition, that any decision could have that triggering effect except the -- except the

decision in a suit against the first Paragraph IV ANDA filer. That assumption was clearly reflected not only in the regulations but it actually seems to underlie the -- the decisions of the three district courts that at that point had passed on any aspect of the 180-day provision; namely, the West Virginia District Court in the original Mylan case in 1989; the D.C. District Court in the 1989 Inwood case; and again, the D.C. District Court in the 1997 Mova decision.

Q. And what is the basis of your opinion that on January 23rd, 1998, there was a substantial possibility that a decision in the Schering-ESI litigation would trigger the running of any 180-day exclusivity to which Upsher was entitled?

A. Foremost would have to be the fact that on June 17th and 18th -- on June 17th, FDA -- FDA announced that it would be interpreting the statute to that -- to that effect. The -- an agency interpretation of the statute that it administers always carries a certain amount of weight with -- with the reviewing court, and this could be expected to carry some weight at least as well.

In addition, the theory or the interpretation, when you look at the actual language of the statute, doesn't appear to -- on its face to be necessarily

inconsistent with the statute, contrary to the way the Mova District Court and the Inwood Court had viewed FDA's -- FDA's attempt to impose prerequisites to 180-day exclusivity that were not stated in the statute.

Q. Okay. Now, you've stated that in your opinion, the possibility that a decision in the Schering-ESI litigation would have triggered any exclusivity by Upsher as of January 23rd, 1998 was substantial. Is that correct?

A. A substantial possibility, yes.

Q. Okay. And what do you mean by "substantial"?

A. Well, it's a very hard word to define and really I suppose covers a range of anything from a mere possibility or a remote possibility on up to somewhere short of a certainty.

Q. Okay. And why do you believe that on January 23rd, 1998, the possibility that that -- that the Schering-ESI litigation would trigger any Upsher exclusivity was substantial?

A. Again, because of the fact that FDA was now taking -- itself was now taking this position, a position that would therefore get at least some -- some deference, and the fact that it wasn't facially inconsistent with the statute.

Q. Now, I'd like to move on to the last question that you were asked about. Have you considered the question of whether Upsher is currently entitled to a 180-day exclusivity period for its 20 milliequivalent potassium chloride extended release tablets that blocks the FDA from approving any other manufacturer's generic version of that product?

A. Yes, I have.

Q. And are you prepared to offer your opinion today on that question?

A. I am.

Q. And what is your opinion as to whether Upsher is currently entitled to 180-day exclusivity for its 20 milliequivalent potassium chloride extended release tablets that blocks the FDA from approving any other manufacturer's generic version of the product?

A. I'm sorry, what is my basis?

Q. What is your opinion?

A. My opinion is that Upsher unquestionably is entitled to exclusivity.

Q. Okay. As of? And as --

A. Currently -- currently it is unquestionably entitled to exclusivity.

Q. And in your opinion, when did that exclusivity become clear?

A. Not -- not later than June 1st, 1998.

Q. And why did that become clear as of June 1st, 1998?

A. Because that was the date on which the U.S. District Court in D.C. issued a permanent injunction enjoining FDA from applying or enforcing the successful defense requirement in its regulation.

Q. What communication, if any, was there from FDA to Upsher-Smith concerning final approval by FDA of Upsher's abbreviated new drug application to market its 20 milliequivalent potassium chloride extended release tablets?

A. Well, if I recall correctly, there was an approval letter sent by FDA to Upsher stating that its ANDA was approved.

Q. Could we pull up CX 59, please.

Your Honor, CX 59 also is previously admitted into evidence.

JUDGE CHAPPELL: Thank you.

BY MR. NARROW:

Q. Mr. Hoffman, do you recognize CX 59?

A. Yes.

Q. And what is it, please?

A. It's the letter I just described.

Q. Okay. Please point out where the letter

indicates that Upsher-Smith has approval from the FDA to market its 20 milliequivalent potassium chloride extended release tablets.

A. In the last paragraph on page 1 of the letter, the second sentence which begins on the third line, it says, "Accordingly, the application is approved."

Q. Okay, thank you.

Now, what additional communication, if any, did the FDA send to Upsher regarding its final approval of the product and its entitlement to 180-day exclusivity?

A. I believe FDA subsequently sent a second letter to Upsher informing it that it did -- it was entitled to 180-day exclusivity.

Q. Would you please call up CX 611.

Your Honor, CX 611 also has previously been admitted into evidence.

Mr. Hoffman, do you recognize CX 611?

A. I do.

Q. And what is it?

A. It's the second letter to Upsher that I just described.

Q. And would you point out where CX 611 clarifies that Upsher has 180-day exclusivity for its 20 milliequivalent potassium chloride tablets?

A. At the top of the second page of the letter,

the first three-four lines.

Q. Okay. Now, what recent confirmation, if any, do you have that Upsher currently is entitled to 180-day exclusivity on its 20 milliequivalent extended release potassium chloride tablets?

A. Well, I'm not sure exactly when it first appeared, but the online electronic version of the Orange Book states that Upsher -- Upsher has 180 -- has 180-day exclusivity or states in substance that FDA (sic) has 180-day exclusivity.

Q. Okay, at this point we are going to put up CX 1653 on the ELMO just to identify -- can we zoom it down so we can get the whole first page on it?

If you would take a look at CX 1653, do you recognize this?

A. Well, this is a collection of pages from the FDA website which lead in the end to pages from the -- printouts of pages from the electronic Orange Book.

Q. Okay. Now, does CX 1653 in any place indicate the status of Upsher's entitlement to 180-day exclusivity?

A. Yes, it does.

Q. And where does it indicate that? If you would please identify the page by the FTC numbers at the bottom, it might be easier for us to put them up on the

ELMO to look at.

A. Well, the third page from the end of the exhibit, which is Bates number FTC 0022686. I'm not sure if this is actually part of the Orange Book as such, but in any case, it shows the -- from the list of approved drugs in any case, the Upsher-Smith 20 milliequivalent potassium chloride product with the application number, the ANDA number, 074726.

It then invites the user to click at a certain place for patented exclusivity info, and clicking at that place brings up page -- Bates page 0022687, which indicates that it's the patented exclusivity search results, the query on that application number, and states under the heading Exclusivity Data the application number and exclusivity expiration of February 28, 2002, along with the exclusivity code PC, which is itself explained on the last page of the exhibit, Bates page 0022688. In the alphabetical list of abbreviations, PC equals patent challenge.

My -- I have seen documents in this proceeding stating that Upsher began to market its 20 milliequivalent potassium chloride product on September 1st, 2001, which is exactly 180 days before February 28th, 2002, and from this I conclude that FDA -- the electronic Orange Book shows that Upsher has 180-day

exclusivity that is still running, has not expired.

Q. And when will that exclusivity expire according to the Orange Book?

A. February 28th, 2002.

Q. Okay. Very briefly, I'd like to turn to page 22686, which you had mentioned before. There's a reference on that page to a TE code --

JUDGE CHAPPELL: Mr. Narrow?

MR. NARROW: I'm sorry?

JUDGE CHAPPELL: What exhibit is this?

MR. NARROW: This is the same exhibit, Your Honor. This is CX 1653.

JUDGE CHAPPELL: Thank you.

MR. NARROW: This is just one of the pages that Mr. Hoffman had referred to a few moments ago while we were discussing this exhibit.

BY MR. NARROW:

Q. On page 0022686, do you have that page, Mr. Hoffman?

A. Yes, I do.

Q. There's a reference on that page to TE. Do you see "TE Code"?

A. Yes, I do.

Q. And what does TE mean?

A. My understanding is that it stands for

therapeutic equivalence.

Q. And to the right of that, there is a capital AB. Do you know what that means?

A. Yes, I do.

Q. And what does that mean?

A. AB is the code that FDA assigns in the Orange Book to generic products that it deems therapeutically equivalent to the -- to the brand name drug on which the generic, let us say loosely, is based, and for that -- and for that matter, AB -- all generic AB products are considered by FDA to be therapeutically equivalent to each other with the result that, as I believe Dr. Levy testified earlier, a pharmacist is free or in some states required in most circumstances to substitute a generic for -- where a prescription is written for the brand name product by brand name.

Q. Does this reference here have anything to do with the concept of pharmaceutical products being AB rated?

A. I -- that -- the -- that -- the term "AB rated" refers to the assignment by FDA of an AB therapeutic equivalence code for products it deems to be therapeutically equivalent and therefore substitutable.

Q. Okay. Now, what is ESI Lederle's current approval status from the FDA concerning its 20

milliequivalent extended release potassium chloride tablets?

A. To the best of my knowledge, ESI Lederle has an ANDA that is tentatively approved.

Q. Okay. And how do you know that ESI's product is tentatively approved?

A. The list of drug approvals that's part of this exhibit at Bates page 00226 -- 679 shows about halfway down the page that ESI Lederle has an ANDA for -- or has a potassium chloride extended release 1500-milligram 20 milliequivalent product that was tentatively approved on May 11th, 1999.

Q. Okay. Page 22679, I'm also using the previous page, the column headings on 678, indicates that there is an approval letter that was sent to ESI. Is that correct?

A. Well, the column heading says "Letter Posted."

Q. "Letter Posted"?

A. Yeah.

Q. Have you seen the letter that was sent to ESI?

A. Yes, I have.

Q. Is that letter included in the FDA website in this same exhibit, by the way?

A. Yes, it is, on Bates page -- the very next Bates page in the exhibit, 0022680.

Q. Can we also put on CX 612 at this time?

CX 612 also has previously been admitted into evidence, Your Honor.

JUDGE CHAPPELL: Okay.

BY MR. NARROW:

Q. Do you recognize CX 612, Mr. Hoffman?

A. Yes, I do.

Q. What is it?

A. It appears to be a photocopy of the actual tentative approval letter sent to ESI as opposed to the version of the letter that I pointed to a couple of minutes ago, which is just I guess an electronic printout of the text of the letter.

Q. In CX 612, could you please point out where that letter indicates ESI's tentative approval for its 20 milliequivalent potassium chloride tablets?

A. In the third paragraph beginning in the fourth line, "Accordingly, the application is tentatively approved."

Q. Okay. And where in CX 612 does it indicate that ESI's final approval is subject to 180-day exclusivity of a prior Paragraph IV ANDA filer?

A. On page 2 of Exhibit 612, the second new paragraph after the indented paraphrase or rendering of the statutory language, is a statement to that effect.

And the paragraph that follows that.

MR. NARROW: At this time, Your Honor, I would move admission of CX 1653, the electronic Orange Book -- the FDA web site and electronic Orange Book document that we have just been discussing prior to CX 612.

MR. NIELDS: No objection, Your Honor.

MR. GIDLEY: No objection, Your Honor, to the Orange Book, and the only thing I would like to state clearly on the record is by agreeing to the admission of the Orange Book, in no way is Upsher-Smith agreeing that had there been a litigation during the 180 days what the result would be. We simply are agreeing to the admission of the Orange Book for what it says.

JUDGE CHAPPELL: Okay. What's that exhibit number?

MR. NARROW: The exhibit number is CX 1653, Your Honor.

JUDGE CHAPPELL: CX 1653 is admitted.

(Commission Exhibit Number 1653 was admitted into evidence.)

BY MR. NARROW:

Q. Now, Mr. Hoffman, you stated that ESI received tentative approval from the FDA on May 11th, 1999. Is that correct?

A. That is -- that is what the approval letter states, yes.

Q. And ESI has not yet received final approval. Is that correct?

A. Not to my knowledge.

Q. Now, in view of your statement that Upsher-Smith has 180-day exclusivity that currently is running and that would expire February 28th, 2002, when is ESI eligible for final FDA approval?

A. On the expiration date or perhaps it's the day after, I'm not sure.

MR. NARROW: Your Honor, I would move at this time the admission of CX 1656, which was the second demonstrative time line that was put up concerning the court decision trigger, with the same caveat under which CX 1655 was admitted, if that's acceptable.

MR. NIELDS: Your Honor, I don't think I've got an objection to it, but it seems to me that the date should be changed where the witness has indicated it was incorrect. It is incorrect. The guidance letter is dated July 29th, 1988 -- and they have now taken it off the screen, so I can't talk about it anymore.

MS. HERTZMAN: I was just going to change -- excuse me, Your Honor, I was just going to change the date to the correct one.

MR. NARROW: I certainly have no objection to it being admitted in corrected form or current form with the testimony indicating the correction.

MR. NIELDS: It would be useful --

JUDGE CHAPPELL: We are not -- we don't want to be changing exhibits on the fly.

MS. HERTZMAN: Okay, I apologize.

JUDGE CHAPPELL: I understand you have good intentions. Let Mr. Nields finish what he's saying, and then we need to hear from Mr. Gidley, and then we'll decide.

MS. HERTZMAN: Okay.

MR. NIELDS: It would also be useful if the time lines -- again, she has taken it off the screen, but the time lines are close, but they are clearly not in the right place. For example, there's an April '98 date they've got somewhere around September, and there's a similar problem with the '97 dates.

Again, all I'm saying is that if we're going to fix the date, which I would suggest we do, Your Honor, these time lines ought to be lined up a little bit in closer approximation to the dates that they're supposed to match.

MR. GIDLEY: Your Honor, no objection as a demonstrative for identification purposes summarizing

the witness' testimony, as before.

JUDGE CHAPPELL: Okay. I think the witness testified the date was wrong, so I think just have the witness correct it, and then mark it for identification, and with the stipulation I've just heard, it's admitted.

MR. NARROW: Thank you, Your Honor.

JUDGE CHAPPELL: What's the exhibit number?

MR. NARROW: That is CX 1656, Your Honor.

JUDGE CHAPPELL: Okay, CX 16 -- what?

MR. NARROW: 1656.

JUDGE CHAPPELL: Okay, with the understanding that the witness will correct it as he testified to, CX 1656 is admitted.

MR. NARROW: Thank you, Your Honor.

(Commission Exhibit Number 1656 was admitted into evidence.)

JUDGE CHAPPELL: I would like it corrected with a strike-through, not as an original. Is that clear?

MR. NARROW: Yes, Your Honor, we will do that. Thank you. At this time, Your Honor, I have no further questions for Mr. Hoffman.

(Discussion off the record.)

CROSS EXAMINATION

BY MR. NIELDS:

Q. Good afternoon, Mr. Hoffman.

A. Good afternoon, Mr. Nields.

Q. I'm not going to ask you any questions about statute numbers and symbols.

A. I'm grateful.

Q. But I am going to ask you at the beginning a couple of questions that compare your opinions to the allegations in the complaint.

I've put up a -- on the screen an exhibit that shows an allegation in the complaint, it's complaint paragraph 29, and it reads, "At all times relevant herein, FDA final approval of an ANDA for a generic version of K-Dur 20 for anyone other than Upsher-Smith was blocked."

Then I've put up something from your expert report of August 15th at page 4, which states, "On June 17, 1997, the date of the Schering/Upsher agreement, there was substantial uncertainty whether Upsher was entitled to a 180-day exclusivity period."

My first question is, does that correctly state your opinion at the bottom of this exhibit?

A. Yes, it does.

Q. And then I would ask you if the date of the Upsher-Schering agreement is relevant herein -- I'll just ask you to assume that -- then, in fact, I take it

one cannot say that ANDAs for generic versions of K-Dur 20 for anyone other than Upsher-Smith were blocked. In fact, there was substantial uncertainty about that. Is that correct?

A. Those are not inconsistent statements. I believe -- I believe you've stated a non sequitur.

Q. Okay. Before I go to the next comparison, I'm going to show you Exhibit 636 -- well, let me just ask this before I go to it.

I take it the reason there was substantial uncertainty was because, as you've testified on direct, the successful defense regulation was, as you said, still on the books, at least that's one of the reasons for the substantial uncertainty.

A. That was one of the factors creating the substantial uncertainty.

Q. Now, I'm going to put on the ELMO CX 636, which is from The Pink Sheet in May. You've testified about this already. This is the document in which you indicated there was publication of the FDA's acquiescing in the Mova decision of the District Court. Do you recall that?

A. Yes, I do.

Q. I think there were some parts that were not shown on the screen or read during your direct, and I

want to do so now.

One of the statements there is, "FDA is 'unhappy with the outcome of (the Mova) case. We do not think it's consistent with the intent of the statute.'"

I take it it's your understanding that that was FDA's position in May of 1997.

A. Yes, it is.

Q. And then it says down below, "Right now, we are acquiescing to the Mova court decision, but for those of you who think you know what that may mean with respect to ranitidine, please don't go running out of here and say you know the answer, because it's far more complicated than that."

My question is this: Is it correct that FDA's position as announced to the public was right now, they were acquiescing in Mova?

A. Yes, meaning at that -- meaning at that time, at the time of the statement.

Q. I'm putting up two other allegations from the complaint on the screen. The first one reads, "If the first firm filing an ANDA loses its patent litigation with the patent holder, no firm is given a 180-day Exclusivity Period."

As the law stands today, Mr. Hoffman, do you

agree with that?

A. As the law stands today, I do not agree with it.

Q. And indeed, you have so testified at your deposition, correct?

A. I'm sorry? Say it again, please.

Q. I said, indeed, you have so testified at your deposition.

A. Yes, I have I believe.

Q. And you testified at your deposition:

"QUESTION: Is it your opinion...when a brand name company sues the first filer for infringement and the first filer loses, the first filer is nonetheless entitled to exclusivity under the statute?

"ANSWER: Under the law as it stands today, yes."

Then you were asked, "In your opinion, if Schering had litigated the case against Upsher to conclusion and won, Upsher would have been entitled to exclusivity?"

Your answer is, "Under the law as it stands today, yes."

Do those two statements correctly state your opinion?

A. Yes, they do.

Q. Now, I'm putting back up one of the quotes from the previous slide and one of the question and answers that you gave at your deposition. The complaint says, "If Schering had prevailed [in the patent litigation] Upsher would not have been eligible for 180-day Exclusivity Period."

Then you state:

"QUESTION: In your opinion, if Schering had litigated the case against Upsher to conclusion and won, Upsher would have been entitled to exclusivity?

"ANSWER: Under the law as it stands today, yes."

I think you've already said that your opinion differs from the allegation in the complaint on this point.

A. Well, my opinion is under the law as it -- as it stands today. If -- if we read the complaint as relating to the law as it stands today, yes, my opinion is different from that stated in the complaint.

Q. Now, your deposition testimony was given on November the 9th, correct, of last year?

A. I don't have a current recollection of the exact date, but it was sometime last fall.

Q. Now, on November the 9th, we have a response to an interrogatory by complaint counsel, which states,

"If Schering had won the litigation, Upsher would not have qualified for the 180-day exclusivity period."

So, under the law as it stands today, you disagree with that, correct?

A. Yes, I do.

Q. And then following November 9th, after your testimony, there's a revised interrogatory response by complaint counsel dated December 28th. It says, "If Schering had won the litigation, Upsher may not have qualified for the 180-day exclusivity period."

Do you see that?

A. Yes, I do.

Q. You actually disagree with that, too, I take it.

A. Well, it -- again, if this is taken as a -- if this is intended to reflect the law as it stands today, I would disagree with it. If it were intended to reflect the state of the law prior to June -- on or prior to June 17th, 1997, it -- it's not a bad statement of how things stood.

Q. But just so we're clear, on November 9th, complaint counsel said, if Schering had won, Upsher would not have qualified, and then after your deposition, they say, if Schering had won, Upsher may not have qualified, but that change still doesn't get

to your opinion.

A. Well, it doesn't get to my opinion as the law stands today, which is not the way the law stood on June 17th, 1997.

Q. Now, Mr. Hoffman, your opinion about the way the law stands today in a case where the first filer loses the patent litigation is squarely the opposite of the position taken by FDA, isn't it?

A. Of the position taken by FDA?

Q. Yes.

A. Not to my knowledge, no.

Q. I've put up a -- on the board two statements by the FDA. The first one is a regulation. Do you see that?

A. Yes, I do.

Q. And the regulation reads, "An applicant who has submitted a certification paragraph [IV]," that's the certification you testified earlier where you say -- where the first filer or filer says we don't infringe a valid patent, correct?

A. Correct.

Q. It goes on, "and is sued for patent infringement, within 45 days of the receipt of notice sent under Section 314.95 shall amend the certification if a final judgment in the action against that

applicant is entered finding the patent to be infringed."

Do you see that?

A. Yes, I do.

Q. "In the amended certification, the applicant shall certify under paragraph [III] that the patent will expire on a specific date. Once an amendment or letter for the change has been submitted, the application will no longer be considered to be one containing a certification under paragraph [IV]."

Do you see that?

A. Yes, I do.

Q. And that happens if the first filer loses the patent infringement case, correct?

A. Not necessarily. The regulation states what it states, but that does not mean that any particular first filer actually does submit a -- an amendment or a letter for the change, to use the words of the regulation.

Q. It says here supposed to, correct?

A. Well, I'm hesitating because I'm not sure what you mean by "supposed to." This regulation could be read that way; however, FDA consistently read it in the course of the Granutec and Mova lawsuits as being what it called a housekeeping regulation that didn't require

anybody to do anything.

Q. I was getting to that. They did take the position in Mova that it was simply a housekeeping regulation that didn't affect 180-day exclusivity rights, correct?

A. Well, they said it was a housekeeping regulation that -- I don't believe they phrased it exactly that way, but they said it was a -- it was a housekeeping regulation, and they rejected or disagreed with the argument that I think you're advancing now.

Q. And isn't it true that since then, FDA has changed its position, and its current position is that if -- that this regulation requires a loser to change its certification from Paragraph IV to Paragraph III and that upon making that change, the loser is no longer eligible for 180-day exclusivity? Isn't that true?

A. Once -- once -- FDA has taken the position that once that change is made, that would be the case. FDA -- FDA took that position and -- in addition to a slight variant or maybe not so slight variant of that position in the letter to Teva, T E V A, Pharmaceuticals that's also on the screen, but its interpretation was actually rejected by the U.S. District Court for the Northern District of West

Virginia.

Q. Now, I'm talking just about the case where the -- where the first filer loses the patent infringement case. Do you have that in mind?

A. Yes, I do.

Q. I'm not talking about a settlement. I'm talking -- yet. I'm talking about a case where the first filer is sued for patent infringement and loses.

A. Okay, I'm sorry, I thought you were talking about what's stated in this -- in this regulation that either is or isn't a housekeeping regulation.

Q. Well, let's take it one at a time, okay? The housekeeping -- what you call the housekeeping regulation --

A. Excuse me, Mr. Nields, it's not what I call the housekeeping regulation; it's what FDA called the housekeeping regulation.

Q. Wouldn't it be fair to say, Counselor, what FDA called a housekeeping regulation during the Mova oral argument?

A. I thought that's what I said, and I'm sorry if I was acoustically unclear.

Q. Okay. The regulation says that an applicant who has submitted a Paragraph IV certification and is sued for patent infringement shall amend the

certification if a final judgment in the action against that applicant is entered finding the patent to be infringed. That's the regulation, correct?

A. That's what the regulation says, yes.

Q. And then, recently -- namely, in the Teva letter that you referred to -- FDA says, "Applicants who change from a paragraph IV to a paragraph III are no longer eligible for 180-day exclusivity."

Isn't that also true?

A. Well, I don't have the Teva letter before me, it's a rather long letter, but I am -- my impression is that there is a statement to that effect in the letter, yes.

Q. Well, two things should happen now. One is I should tell you that the Teva letter is at tab 9 of the notebook that's in front of you, and second, I'm going to put it on the ELMO.

Is that legible, Your Honor?

JUDGE CHAPPELL: Yes.

BY MR. NIELDS:

Q. I'm going to ask you if the following doesn't appear in the Teva letter at page 4:

"Under certain circumstances, an ANDA applicant is required to amend its patent certification if the patent is determined to be infringed," then it goes on

and the next sentence says, "If an applicant changes from a paragraph IV certification to a paragraph III certification, the ANDA will no longer be eligible for exclusivity," citing a case.

Do you see that?

A. Yes, I do.

Q. So, wouldn't it be fair to say, sir, that FDA's current position is that if a first filer is sued and loses, that it is required to change its certification from a IV to III and that upon doing so it is no longer entitled to exclusivity?

A. Well, I don't know that I can agree with that, Mr. Nields, because the sentence that you've quoted really doesn't seem to be significantly different from the sentence in the regulation itself, which on one reading also -- and perhaps by its terms, I don't have the regulation before me -- says that the applicant is required under certain circumstances to amend, and I'm not -- without having the two before me to compare, I'm not sure exactly how different that is from the regulation. The -- which was previously stated to be a housekeeping regulation.

So, whether this letter purports to impose an affirmative duty on applicants that was not there before, I don't know, but if it did purport -- if it is

a new interpretation that purports to impose a new duty, I have very serious question in my mind whether that interpretation is legally valid. And I would -- for procedural reasons, and I would be happy to tell you why if you wish.

Q. No, I first want to get at your answer a moment ago. I'm going to suggest something to you that this letter adds to the regulation. Are you ready?

A. I'm ready.

Q. This letter adds the statement, "If an applicant changes from a paragraph IV certification to a paragraph III, the ANDA will no longer be eligible for exclusivity."

It is no longer a housekeeping regulation once the FDA says it has that consequence, is it?

A. Well, that depends on whether FDA is procedurally, legally entitled to make a change with that -- having that consequence, and I do not believe they are simply by writing a letter.

Q. Well, I've -- so far I've only asked you whether your opinion is squarely at odds with FDA's position. I haven't asked you yet whether FDA's position is legally valid. I've only asked you whether your opinion is squarely at odds with that of the FDA.

A. Well, my opinion did not attempt to address the

situation where a first Paragraph IV ANDA filer prior to the -- either the commencement or the end of 180-day exclusivity period affirmatively changes the certification from a paragraph IV to a paragraph III. That's a separate question. And I have not addressed the question whether under the law at any point in time whether that kind of a change would obviate exclusivity if it were -- if the change were actually made.

Q. So, you don't think -- your opinion is not at odds with this in the case where the first filer gets sued and loses the patent litigation?

A. No, I didn't say that either. I said that my opinion simply didn't address this particular set of facts.

Q. Well, then, let me ask it of you now. Do you agree with FDA's position as stated here, that -- and let me state it for you just so it's really clear -- that -- do you agree with this position, that when a first filer loses a patent infringement litigation, it shall amend to a Paragraph III and that upon doing so the ANDA will no longer be eligible for exclusivity?

A. Well, those -- again, those are two separate -- two separate clauses and two separate questions. We can take them --

Q. Let's take them one at a time.

A. I'd appreciate that.

Q. Let's take them one at a time. Do you agree with this statement: An ANDA applicant -- first filer who is sued and loses is -- shall change their certification from a Paragraph IV to a Paragraph III?

A. If that means anything different from what the regulation actually says on that precise point -- see, when FDA called this a housekeeping regulation, it was in response to the very argument you're making, which is that the regulation imposed a requirement of making the change, and FDA said no, it doesn't.

Now, simply by making this statement in the letter, that in and of itself doesn't tell me whether FDA has now changed its -- its interpretation of the regulation to impose a duty.

Q. Counselor, do you want to take these two questions one at a time or both together? I'll do it either way.

A. I was trying to take them one at a time, Mr. Nields, but I'm sorry if I failed to do so.

Q. Well, when I put them together, you ask me to do them one at a time. When I ask you then the first half, you respond then to the second. Let's see if we can stick -- either way, which way do you want to do it?

A. Well, they're interrelated, and it depends on exactly what question you're asking me.

Q. That's why I asked them together, because they're interrelated. Let's go back to asking them together because they're interrelated.

Do you agree with FDA's position that when a first filer loses a patent suit, it must change to a Paragraph III, and upon doing so, it loses all rights to exclusivity?

A. For reasons that I've tried to explain but which you haven't let me explain in full, I don't agree that as a matter of law, notwithstanding this letter, an FDA -- an applicant is required to change. If an applicant did change, then I think it -- you can argue it either way as to whether the ANDA is any longer eligible for exclusivity.

Q. I didn't ask you about what the law said. I asked you what FDA's position is, and then I asked you if you agreed with it.

A. Well, again, and I'm -- I don't mean to seem obstinate, but from -- just from that first sentence, I cannot -- just from that first sentence, standing alone, I can't tell if FDA is or is not making a change from its prior interpretation -- its prior interpretation of the regulation, which uses I think

substantially identical language. So, I guess I can't tell you what FDA means by that first sentence, whether they mean to be imposing an obligation or to change or to amend.

Q. Well, let me see --

A. I'm willing to assume it either way you want for purposes of discussion, but from that sentence, I don't think I can tell that they actually do mean that.

Q. Well, let me see if I can help you. The FDA regulation that you've testified about says that the loser must change the certification to a Paragraph III, but it doesn't state that the consequence of that will be to lose exclusivity rights.

A. Oh, I think it -- I think it implies that very clearly in the subsequent sentence.

Q. Which sentence?

A. The one immediately following that says, "Once a letter -- an amendment or a letter for the change has been submitted, the application will no longer be considered to be one containing a certification under Paragraph IV."

Q. So, you think that the rule does have the consequence that the first filer loses its exclusivity rights?

A. I think that is one reading of the regulation.

It's a reading that FDA rejected in both the Granutec and the Mova cases.

Q. And now I'm going to ask you, isn't it the case that FDA clearly endorses that reading in the Teva letter that is now on your screen on the ELMO when it says, "If an applicant changes from a paragraph IV certification to a paragraph III certification," listen to these words, sir, "the ANDA will no longer be eligible for exclusivity"?

Is that hard to understand?

A. No, it's not hard to understand, Mr. Nields, but I'm sorry I'm finding you hard to understand.

Q. This conversation we're having about FDA's position when the first filer loses the suit turns out to be quite important to what happens if the first filer settles. Isn't that true?

A. That could be argued.

Q. Because isn't it a fact that in this very same letter, FDA takes the position that when the first filer settles the lawsuit, it also loses its exclusivity rights?

A. Is that a question, sir?

Q. Of course.

A. I'm afraid I lost the thread of exactly what the question was. I heard the statement, but I think I

missed the question.

Q. Isn't it true that in this very same letter that FDA takes the position that when a first filer settles a lawsuit, it loses its exclusivity rights?

A. No, I don't think that's a fair statement of the letter. The -- and if I may explain why I don't think it's a fair statement of the letter, it is because the letter identified at least one additional factor that led it to the conclusion that in that particular matter, the exclusivity had been lost -- entitlement to exclusivity had been lost.

Q. Well, let's see if we can't find a nice, clear statement in the letter to look at. I've put it up on your screen. It says, "The Mylan/Pfizer settlement effectively changed Mylan's patent certification from a paragraph IV to a paragraph III, and thus Mylan has lost its eligibility for exclusivity."

Is that clear enough for you?

A. It's a very clear statement of one sentence in a seven-page letter, yes.

Q. And sir, isn't it a fact that that position of FDA was rejected in a court suit but that FDA's position remains the same today?

A. I have no idea whether FDA's position remains the same after its -- after its -- its statement to

that effect was overruled in the court suits.

Q. Well, let's take a look at the brief that FDA wrote in the Fourth Circuit on appeal after the District Court had ruled against it. You're familiar with this brief, aren't you?

A. Yes, I am.

Q. And it says here, "Mylan did not lose the litigation but settled before the court issued a judgment." Then it says, "The effect of the settlement and losing the patent litigation are essentially the same: The patent litigation ended without opening the door to approval of competing ANDAs. Thus, Mylan, like the ANDA applicant in the above regulation, should be considered to have amended its certification."

Did FDA write that in a brief to the Fourth Circuit?

A. Well, not to be cute, I think the Justice Department wrote it in a brief submitted on behalf of FDA, but it has a familiar ring, and I -- yes, I believe that's what was in the brief. That was dated, as the slide points out or the ELMO, excuse me, on July 25th, 2001.

Q. And that was before you submitted your expert report, wasn't it?

A. Yes, it was.

Q. You didn't say a word about FDA's position on settlements expressed in that brief in your report, did you?

A. Oh, I believe I did, sir.

Q. Oh, let's find it. Your report is in front of you at tab 1. Show me where -- show us where you told us about FDA's positions on settlement expressed in either this Teva letter or the brief on appeal.

A. I didn't refer specifically to settlements. I did refer to the -- to the -- to the District Court decision overruling FDA's position and also to the brief on appeal as -- that would be at page 15 of the report in --

Q. Let's take 15 and put it right up here on the ELMO, and show us -- show us what you told us about FDA's position on settlements in your report, sir.

A. Well, as I said, I didn't purport to address settlements specifically. What I did address was whether FDA might adopt a new interpretation of the statute not resulting in a 180-day exclusivity period for Upsher, which is -- I'm virtually reading from the -- from the report.

The -- clearly, one of the facts in the Upsher -- Schering-Upsher situation is that Upsher -- Schering and Upsher settled the lawsuit. So that when

I referred to new interpretations that would not -- that would not result in an exclusivity period for Upsher, I was intending to refer to all the factors -- all the facts -- factual components of the Schering-Upsher situation.

I think this might be a good time -- and I think this is a -- by way of providing a full answer to your question, even if FDA were to adopt a new interpretation of the statute that would in future cases keep Upsher -- a person or a firm in Upsher's situation from being entitled to exclusivity, that does not necessarily mean that Upsher would -- I'm sorry, that FDA would apply the same interpretation to preexisting situations, preexisting settlements, preexisting awards of exclusivity.

And in fact, in other documents being issued by FDA over the last couple of years, FDA has indicated a disinclination -- this is expressly stated -- that it is not inclined to apply these kinds of new interpretations retrospectively; that is, to prior -- to prior settlements, prior awards of exclusivity.

Q. You were aware when you wrote the report that this case involved a settlement, weren't you?

A. Yes, I was.

Q. But on the page of your report that you

identified, you didn't even use the word "settlement."

A. No, I didn't.

Q. And you didn't disclose anything about what FDA had said on the subject of settlements in the Teva letter or in the Fourth Circuit brief.

A. No. Would you like to know why?

Q. I'm going to show you the Upsher letter that I think you testified on direct was FDA awarding Upsher exclusivity rights. Do you have that in mind?

A. Yes, I do.

Q. It's dated, by the way, January 28th, 1999, and it says in the second paragraph on the first page, "Your application contains a patent certification under Section," da-da-da, "IV," that's Paragraph IV, right?

A. Yes.

Q. Then it says, "You subsequently informed the Agency that Key Pharmaceuticals initiated a patent suit against you," identifying the court, and then it says, "You have also notified the Agency that on July 24, 1997, the New Jersey court issued a stipulation and order of dismissal terminating the litigation with Key Pharmaceuticals, Inc."

Do you see that?

A. Yes. I'm not sure if that's the end of the sentence or if it's continued --

Q. It is the end of the sentence, that's why I'm turning the page. I'll show you the next page in a moment, but it starts a new sentence.

Do you see that?

A. Yes, I do.

Q. There is no reference to a settlement there, is there?

A. Well, the word "settlement" is not used, but the word "stipulation" is used.

Q. True.

A. And to me, a stipulation implies agreement which is another word for settlement.

Q. Then we go over to the next page, and at the end of the paragraph -- by the way, there I'll show you, you can see it begins a new sentence.

A. Yes, I do see. I took your word for it, Mr. Nields.

Q. Okay, okay, thank you.

Then we go down to the bottom of that paragraph and it says, "The Agency expects that you will begin commercial marketing of this drug product in a prompt manner."

Do you see that?

A. I do.

Q. Would that be consistent with the agency

knowing that the settlement involved an agreement not to market the drug until 2001?

A. Well, for one thing, I don't know what FDA means by a "prompt manner," and again, not to be cute about it, but there are those who believe that the progress of time as measured by FDA is at a fairly glacial pace, but on a -- and I apologize if I seem to be flippant, but it is a little late. The -- I don't know what FDA meant by "prompt," and I do know that as of -- at least as of the time the exclusivity information was posted in the electronic Orange Book, FDA still believed that Upsher had exclusivity.

So, I conclude from that that whatever FDA meant by a "prompt manner" has not interfered with its -- for whatever reason, it has not interfered with -- with its award of exclusivity at Upsher.

Q. There's no -- do you have any reason to think that the FDA knew when it -- when it wrote this letter that Upsher had agreed not to come on the market until September of 2001?

A. I really have absolutely no information one way -- no information one way or the other.

Q. But that was the fact, wasn't it, in the Teva letter, this thing we've been calling the Teva letter, the letter to Teva? I think it dealt with Mylan's

entry. Isn't it true that the factor that led the FDA to say exclusivity should not be given to the first filer is that they observed that the first filer wasn't marketing the drug?

A. That was one of the factors that -- that FDA mentioned.

I would like to -- I think I may have omitted to say one other thing in answer to one of your prior questions, and -- I think the one just before this, that is, the statement in the Teva letter about expecting prompt marketing. That is, I believe, what we might call a boilerplate statement that for some time now has appeared in every one of FDA's letters awarding exclusivity or at least that is my impression. So, whether -- so, I don't believe it was particularly tailored to the circumstances of the -- of the Upsher situation.

Q. Okay, I am going to just touch on one other brief subject, Mr. Hoffman.

You testified about the letters that FDA had sent out around June 17th and June 18th, 1997 in connection with ranitidine. Do you remember that?

A. Yes, I do.

Q. And you testified about a letter that was sent to Lipha Pharmaceuticals as agent for Genpharm. Do you

remember that?

A. Yes, I do. I do remember that.

Q. And you said that FDA gave Genpharm exclusivity rights even though it had settled its case with a stipulation that it did infringe. Do you recall that?

A. I do.

Q. Isn't it true that, in fact, what was going on in that case is that FDA gave Genpharm 180-day exclusivity rights based on an ANDA certifying on a patent as to which litigation was still continuing?

A. Litigation had terminated, and then in -- reinitiated. The situation was reasonably complicated, and I'd be happy to explain it to you if you wish.

Q. Well, why don't we just --

A. But the litigation had -- the litigation that I referred to had terminated. The litigation in which Genpharm was then engaged was separate, new litigation based on a new Paragraph IV certification for a reformulated version of Genpharm's product, which it hoped, unlike the first version, would not infringe the patent.

Now, that second Paragraph IV certification was far from the first Paragraph IV certification for generic Zantac. It was subsequent in time to several others, all of whom ultimately showed up in North

Carolina to litigate.

FDA's position, if I can articulate it, because it was pretty complex, is that the -- it was the first Paragraph IV certification that counted -- that is, the original one which everyone conceded was the first -- so that the litigation that you're referring to related to a subsequent Paragraph IV certification that was -- that was not the first certification that entitled Genpharm to exclusivity.

Q. All right. Now, listen carefully, okay?

A. Okay.

Q. I'm going to ask you if the following isn't correct: That the FDA, in terms of according -- in terms of deciding who was the first filer, used the first ANDA filing of Genpharm, so they gave Genpharm priority based on their first ANDA filing, but the reason they got exclusivity was that there was a later ANDA filing that was still in litigation. Isn't that, in fact, what happened?

A. I don't believe so.

Q. Let's just take a look at the letter, all right? This is the letter to Lipha Pharmaceuticals as agent for Genpharm, and it says here, "ANDA for ranitidine hydrochloride initially contained paragraph IV certifications to both the '658 patent and the '431

patent." Then it mentions a couple of lawsuits. I'm on the bottom of page 1 now.

A. Yes, I understand.

Q. And it --

A. I was just reading ahead.

Q. -- and it says that the lawsuits ended in a final consent on -- excuse me, final judgment on consent, finding the listed patents valid, enforceable and infringed. Then it says, "You subsequently amended your ANDA," and it goes over to the next page, "and submitted a paragraph III certification to the '658 patent and a paragraph IV certification to the '431 patent." Then it says, "Litigation resulting from this certification is underway in the U.S. District Court for the Southern District of New York."

Do you see that?

A. I do.

Q. Isn't that the reason, the fact that there was litigation still ongoing in the Southern District of New York, isn't that the reason they got exclusivity rights?

A. No, it isn't, and I would be happy to explain to you why it isn't.

Q. Certainly.

A. The -- this letter really doesn't lay out

anything in the way of a rationale. It lays out background and lays out FDA's conclusions. In the course of the Granutec litigation, which was precipitated by this letter, FDA elaborated on its rationale, and its rationale was that the -- the original -- the second paragraph IV certification related back to the filing of the -- to the original filing of the ANDA. Without that relation back notion, it would have been impossible to argue that Genpharm was the first filer, Paragraph IV filer, so we have to assume that that's what they -- what they did.

Whether FDA -- whether FDA thought that the -- FDA then argued that even though the certification related back to the original filing, which it had to do to make Genpharm the first filer, it -- it could then -- it didn't need -- it didn't need to go on, because in Genpharm or in the ranitidine situation, FDA, remember, was acquiescing in Mova, which didn't require that there be a successful defense. So, whether Genpharm was continuing to litigate was irrelevant.

MR. NIELDS: I have nothing further, Your Honor.

JUDGE CHAPPELL: Mr. Nields, what time do you need to leave? What time are you leaving?

MR. NIELDS: I was planning to leave in a couple of minutes, Your Honor.

JUDGE CHAPPELL: And it is after 6:00 p.m., and it's my understanding that the parties have agreed to proceed on to finish with this witness tonight. Mr. Nields, what if there is recross?

MR. NIELDS: I think I have to rely on my extremely able colleague, Your Honor, on that. I think I'm -- I'm willing to -- I understood the -- that this would be part of the deal when I agreed to it earlier, Your Honor.

JUDGE CHAPPELL: I just want to make sure on the record.

Any objection to Ms. Shores conducting any recross of this witness?

MR. NARROW: Complaint counsel has no objection, Your Honor.

MR. GIDLEY: We have no objection, Your Honor.

JUDGE CHAPPELL: Okay. At this time, Mr. Nields, you've concluded your cross exam?

MR. NIELDS: I have. Your Honor, may I be permitted to address one housekeeping kind of issue before leaving?

JUDGE CHAPPELL: Yes.

MR. NIELDS: Thank you very much.

Yesterday afternoon, we were served in court with a motion to either preclude or limit the testimony of several of the witnesses that we will be calling at the beginning of our direct case. That was the first we heard about it. We have prepared and filed a memorandum in response to that this afternoon, and we can hand it up to the Court now. I think there's been a copy delivered to chambers, I believe. I simply wanted to bring that to the Court's attention.

There were no -- there was no request for an emergency scheduling, but since our witnesses were going to be called perhaps tomorrow, we thought it would be wise to have a responsive pleading in, and I wanted to let the Court know that we had done that.

JUDGE CHAPPELL: Thank you. And check with your office, because depending on when we end up tonight, we won't be starting at 9:30 in the morning. The court reporter has already advised me of that.

MR. NIELDS: Oh, okay.

JUDGE CHAPPELL: So -- all right, thank you.

MS. BOKAT: Excuse me, Your Honor. Before Mr. Nields leaves, I don't want him to be trapped in this building. He may not know that the door he normally comes in off Pennsylvania Avenue I believe is barred after 6:00, and he needs to go out the 7th Street side

of the building.

JUDGE CHAPPELL: Are you sure you --

MS. BOKAT: I love him dearly, but I don't want him trapped.

JUDGE CHAPPELL: Are you sure he doesn't want to be trapped in the building? Also, my crack staff has informed me, Ms. Bokat, that complaint counsel is responsible after 1900 -- 7:00 p.m., sorry, after 7:00 p.m., complaint counsel is responsible for letting all nonemployees out the side entrance, I think on 6th Street or is that -- 7th Street, and that you'll need to take the visitor badges and turn them in to the guard in the basement, just so we understand.

I think, Ms. Bokat, what you said is anyone who leaves before 7:00 must go out the front door. Is that correct? Which exit is that?

MS. BOKAT: It was my understanding that as of 6:00 p.m., people need to go out the door that gives onto 7th Street, correct?

JUDGE CHAPPELL: That's the -- I call that the middle door, and I thought we had a guard down at the main entrance, which I never use, until 7:00 p.m., but the building has no guard?

Well, someone who works for the FTC should take care of this. It's your witness on the stand. We're

all here accommodating your witness, and I think that we don't want people trapped in the building, and we don't want the guards shooting at us. So, if you would have someone take the badges and help people get out of the building, thank you.

I guess all this was on the record. That's fine.

Mr. Gidley, you may proceed with your cross examination.

MR. GIDLEY: Thank you, Your Honor. I would offer, this may be 20 or 30 minutes, I haven't timed this, and I've got to adjust to the most recent cross. Your Honor, if the witness wants a one or two-minute break to stretch his legs, that's perfectly acceptable to me. We don't need the prep time, but if the witness, given the hour, would like to do that, I am happy to accommodate him.

THE WITNESS: That would be a help, Your Honor.

JUDGE CHAPPELL: Feel free, and let us know when you're ready, Mr. Gidley.

(Pause in the proceedings.)

MR. GIDLEY: May I approach, Your Honor?

JUDGE CHAPPELL: Yes, you may proceed, Mr. Gidley, and you may approach.

CROSS EXAMINATION

BY MR. GIDLEY:

Q. Good evening, Mr. Hoffman.

A. Good evening.

Q. You were retained in this matter in May or June of 2001. Is that correct, sir?

A. As best I recall, yes.

Q. But during the summer of 2001. Is that correct?

A. Well, May or June.

Q. All right. And you wrote your report and concluded the writing of your report in August of 2001. Is that correct?

A. Yes.

Q. And your report is dated August 15, 2001, sir?

A. I don't think it actually bears a date, but I believe that's the date at which I was told it was due and was served.

Q. Let me direct your attention -- I have handed you a binder of exhibits, if I could direct your attention to tab 1, Expert Report of Joel Hoffman, which has been designated CX 72, sir. After the cover page, it says, "Expert Report of Joel Hoffman, August 15, 2001."

Do you see that?

A. Yes, I misspoke.

Q. And that date is correct, that your report speaks as of that date. Is that correct, sir?

A. The report speaks as of that date, yes.

Q. Now, your report answers, sir, four questions. Do I have that right?

A. Yes.

Q. And those questions came to you from Mr. Brad Albert of complaint counsel. Is that correct?

A. Correct.

Q. And those four questions, sir, they appear at page 4 of your report. Is that not correct?

A. Pages 4 and 5.

Q. Well, the four questions are set forth on page 4, correct?

A. Oh, I'm sorry, yes, they are.

Q. And then the summary of your opinion appears on pages 4 and 5. Isn't that correct?

A. Yes, it is. I'm sorry, it is late.

Q. Directing your attention to the first question, sir, at the top of page 4, "On June 17, 1997, the date of the Schering-Upsher agreement, was there 'substantial uncertainty.'" Do you see that language?

A. Yes, I do.

Q. And that phrase, "substantial uncertainty," that came from Mr. Albert. Is that correct, sir?

A. That's my recollection.

Q. And the second question that's posed on page 4, did that question come to you from Mr. Albert?

A. Yes.

Q. Including in the second line, "substantial uncertainty"?

A. Yes.

Q. And sir, just for the record, that question two relates to the status of the Schering-ESI agreement as of January 23, 1998, does it not?

A. Well, the -- it relates to the status of the legal question on the date of the Schering-ESI agreement, yes.

Q. Very good, sir.

Now, you have no idea, sir, where Mr. Albert got the phrase "substantial uncertainty" from. Isn't that correct?

A. That's correct.

Q. And you adopted his adjective, "substantial," modifying "uncertainty," did you not, sir?

A. Well, I didn't adopt it. I attempted to answer the question that he asked, and that was the question.

Q. And sir, as of June 17, 1997, there was substantial uncertainty with respect to the applicability of the 180 days exclusivity, was there

not?

A. That is my opinion.

Q. Now, sir, if you had been retained by Upsher-Smith in June of 1997 and asked if the 180-day exclusivity would apply, you would have told Ian Troup, the head of Upsher-Smith, that you had no idea one way or the other, correct, whether that would apply?

A. I would have told him something to that effect, yes.

Q. You would have told him that you would have no idea whether the 180 days would apply, did you not?

A. Well, you just asked me that, and I just answered it. I would have told him something to that effect. Whether I would have used those precise words, of course I don't know, because he never asked me.

Q. Sir, I'm going to show you, if this appears on the screen, let's see if we can -- and we would be very pleased to hand you the full transcript. What I've done is culled out the question and answer that you were asked at your deposition at page 97. You were asked:

"QUESTION: Sir, if on or about June 17, 1997 Upsher-Smith retained you and asked you if we settle with Schering-Plough today, will we be entitled to 180-day exclusivity in the future, how would you have

answered that?

"ANSWER: I would have said Mr. Upsher-Smith, I have no idea. The state of the law is currently unsettled and evolving at a fairly rapid pace, and I have absolutely no idea."

Were you not asked that question and did you not give that answer at the deposition?

A. I was, and I -- and I did. If you're suggesting that that's somehow inconsistent, I was not perhaps being -- not being flip, but I was giving the substance of what I would have said. Surely no one would think that I was hypothesizing that I would have used those precise words. For one thing, I know there is no Mr. Upsher-Smith, although I suppose there was a Mr. Upsher once and a Mr. Smith.

Q. Do you know who Ian Troup is?

A. I've seen the name. I believe he's an executive with Upsher-Smith, but beyond that, I don't know.

Q. Sir, can you point him out in this courtroom this afternoon?

A. Absolutely not. I've never laid eyes on the gentleman in my life.

JUDGE CHAPPELL: For the record, the witness did not identify Mr. Troup.

MR. GIDLEY: Very good, Your Honor.

BY MR. GIDLEY:

Q. June 17, 1997, that was the date of the Upsher-Schering agreement, was it not, sir?

A. I believe it was.

Q. And in preparing your report, sir, you did not review that agreement in arriving at your opinion. Is that not correct?

A. I do not believe I reviewed the agreement itself, no.

Q. And it's not one of the documents that's listed that you relied upon in Exhibit A to your report. Isn't that correct?

A. Well, subject to looking at the list, I would imagine not, because I don't believe I actually did review it.

Q. All right, sir. Now, the dates June 17, 1997 and January 23, 1998, those were dates that Mr. Albert asked you to focus on, isn't that correct, in your report?

A. Yes.

Q. And the assignment you were given was not to express an opinion as of May 20, 1997. Isn't that correct?

A. Yes.

Q. And your assignment was not as of May 30, 1997, was it, sir?

A. No.

Q. In fact, sir, you were not asked your opinion as to the applicability or the certainty as to the applicability of the 180-day provision at any date between May 1 and June 16, 1997 in the four questions posed in your report, were you, sir?

A. No, I wasn't.

Q. Sir, in presenting your views to the Court today, you are not opining as to what Upsher-Smith actually knew about exclusivity on June 17, 1997, are you, sir?

A. No, of course not.

Q. And you are not opining as to what Schering-Plough knew about exclusivity on June 17, 1997, are you, sir?

A. There is nothing in my testimony that goes to what -- any actual knowledge that any individual at Schering may or may not have had, no.

Q. The actual knowledge of either Upsher-Smith or Schering-Plough is not an issue that you've examined. Isn't that correct?

A. Well, yes, that's correct.

Q. And you haven't examined documents or testimony

or deposition transcripts indicating what the Upsher-Smith executives may or may not have believed about exclusivity as of June 17, 1997. Isn't that correct?

A. Correct.

Q. Now, sir, the June 17, 1997 agreement does not address any exclusivity issue by the terms of the agreement, does it, sir?

A. The June 17th agreement?

Q. Yes, between Schering and Upsher-Smith.

A. I've never seen the agreement, so I can't answer the question.

Q. Sitting here tonight, you have no idea one way or the other. Isn't that correct?

A. Yes.

Q. You spoke on direct about this case, the Mova case. Do you recall that testimony?

A. I do.

Q. Now, the Mova District Court decision in January 1997 did not involve a settling first filer, did it, sir?

A. No, it did not.

Q. Unlike our case, the case before this Court, in Mova, the patent infringement action involving the firm Mova was being litigated at the time of the Mylan ANDA.

Isn't that correct, sir?

A. I -- that's my understanding from the Mova opinions.

JUDGE CHAPPELL: Mr. Gidley, excuse me for a moment, I don't mean to knock you off stride.

Mr. Nields raised the issue of some pending motions regarding he said witnesses that may be called tomorrow?

MS. SHORES: That's correct, Your Honor.

JUDGE CHAPPELL: Would you mind giving me the names of who you intend to call tomorrow? I don't want you to disclose strategy, but it would assist me in prioritizing the pending motions.

MS. SHORES: Certainly. The witnesses who may be called tomorrow would be Tony --

JUDGE CHAPPELL: And I mean the ones subject to this pending motion.

MS. SHORES: You do mean the ones subject to the motion?

JUDGE CHAPPELL: Yes, not all your witnesses.

MS. SHORES: Okay, right. Tony Herman, who is Schering's outside patent counsel in the underlying litigation from Covington & Burling, and the other is Charles "Rick" Rule, who Your Honor heard about in opening statement. He's the gentleman who is the

former head of the Antitrust Division who Schering asked to go to one of the meetings with the magistrate judge.

JUDGE CHAPPELL: Okay, so Herman and Rule tomorrow that are subject to the pending motion.

MS. SHORES: Yes, that's right. I think that's right. There's also John Hoffman who is Schering's in-house counsel. He would also be subject to the motion. I don't think that it's likely that we'll get to him tomorrow.

JUDGE CHAPPELL: The other Hoffman?

MS. SHORES: The other Hoffman.

JUDGE CHAPPELL: Okay, thank you.

MS. SHORES: You're welcome.

JUDGE CHAPPELL: You may proceed, Mr. Gidley. Sorry for the interruption.

MR. GIDLEY: Very good, Your Honor.

BY MR. GIDLEY:

Q. The Mova case, the District Court decision you spoke about in January 1997 -- are you there, sir? We're thinking about the Mova at the District Court. Are you and I on the same page?

A. I'm there.

Q. All right. The Mova case was a preliminary injunctive action, was it not, sir?

A. Well, it was an action for a permanent injunction, which came on initially as a motion for a preliminary injunction.

Q. The reported decision that appears at 955 F. Supp. 128 dated January 23, 1997, that was on a preliminary injunction motion, was it not, sir?

A. I'll take your word for the citation, but yes, the January 23rd opinion was the opinion granting the preliminary injunction.

Q. Well, despite the hour, let's not take my word. Why don't you direct your attention, if you would, sir, very quickly to tab 9 of the binder, and at tab 9 appears USX 767.

A. Got it.

Q. Mova Pharmaceutical Corp. vs. Shalala dated January 23, 1997. Do you see that?

A. Yes, I do.

Q. That was an opinion by Judge Robertson, was it not, sir?

A. Yes, it was.

Q. And just so we have the last Q and A in context, let's see if I can ELMO-ize this. Do you see the phrase, "The patent litigation is still pending," sir, that appears at 955 F. Supp 129?

A. Well, without looking at the volume, I'll

assume that this is an accurate rendition of the -- well, I guess it's just an image of it, isn't it? Yes, I guess that's what it says.

Q. Why don't you take your time --

A. I'm satisfied with that.

Q. And the quote indicates that the underlying patent infringement litigation was still pending, not settled as in this case. Isn't that correct, sir?

A. Yes, as I said before.

Q. And in addition, isn't it the case in an injunctive action that there is a familiar four-prong test for an injunction? Are you familiar with that four-part test here in the District of Columbia?

A. Yes, I am.

Q. And doesn't that four-part test have certain factual issues that get weighed by the District Court?

A. Yes, it does.

Q. And in particular, in the Mova case, wasn't a factor that led to the decision on January 23, 1997, wasn't one of the factors that weighed on the Court the relative size, that is, the small size of Mova relative to Mylan? Isn't that an issue that the Court took into account?

A. Well, the issue that the Court took into account was the balance of hardships as between the

parties, and I believe that the Court did refer to the relative size as -- of the companies as one of the elements in making up that balance of hardships.

Q. And specifically, sir, that was something that the Court considered in the second element of the test, which is irreparable injury, and moving down the page, page 131, sir, appears the following passage:

"In particular, Mova, a small company, will have difficulty competing against the much larger Mylan if Mylan is allowed to enter the generic micronized glyburide market and capture market share while Mova remains entangled with patent litigation."

Do you see that quote?

A. Yes, I do.

Q. And sir, isn't that indicative of one of the factual issues that Judge Robertson considered in arriving at his opinion in January of 1997?

A. That's one of the factual issues that he considered in agreeing to -- or in deciding to issue a preliminary injunction, but as you pointed out, there is a familiar four-part test that involves other factors. Nothing in my -- in the opinion that I've given is related to the question of whether overall a preliminary injunction was or wasn't justified in that case.

Q. I know it's getting late, but if you just stay with my questions, you'll get out of here faster.

In light of your last answer, sir, isn't it the case that the relative size of Mova versus Mylan was something Judge Robertson considered in connection with the second element of the four-part test in the Mova case?

A. Yes, it is. And by the way, I'm in no hurry to get out of here. I'm at your entire disposal.

Q. Very good. Not everyone agrees with you right now.

A. They may have more choice than I do.

JUDGE CHAPPELL: It's looking pretty empty on one side of the courtroom.

BY MR. GIDLEY:

Q. By the way, you haven't really looked at any of the factual evidence in this case in arriving at your opinion; you haven't steeped yourself in the depositions or IHs, the investigational hearings. Isn't that correct, sir?

A. That is certainly true.

Q. Now let's turn to the second paragraph of your opinion, the second question you were asked. That's an opinion as of January 23, 1998, is it not, sir?

A. Yes, it is.

Q. And I'm very happy that you're flipping to tab 1. You may as well direct your attention to page 4 of tab 1, paragraph 2. Are you there?

A. I am.

Q. Now, six or seven months after the June 17, 1997 agreement, you express on page 4 an opinion as of January 23, 1998. Isn't that correct?

A. Yes.

Q. And your opinion, sir, is that whereas there had been substantial uncertainty on June 17, 1997, as of January 23, 1998, there was equally or more uncertainty about the applicability of the 180-day exclusivity period as it relates to that agreement. Isn't that correct, sir?

A. Yes.

Q. And that opinion, sir, appears in summary form at the top of page 5, does it not, sir?

A. Yes, it does.

Q. And is it accurate today that you still believe today that on January 23, 1998, the date of the Schering-ESI agreement, Upsher's entitlement to a 180-day exclusivity period was equally or more uncertain than substantially uncertain, the test that you had analyzed as of June 1997? Is that not correct?

A. Yes. That is to say, that is correct.

Q. Now, when I saw that time line, you testified on direct, sir, about the Mova Court of Appeals ruling, did you not, and that occurred in April 1998?

A. Yes, it did.

Q. And April 1998's about ten months after the June 1997 agreement was entered into. Isn't that correct?

A. Approximately.

Q. And you also testified about the Fourth Circuit's ruling in the Granutec case, did you not, which occurred in early April 1998, did it not, sir?

A. Yes it did.

Q. And again, that's about nine or ten months after the June 17, 1997 agreement was entered into, is it not, sir?

A. Almost ten months, yes.

Q. Now, sir, the D.C. Circuit in the Mova opinion called the Hatch-Waxman 180-day provision, that statutory scheme, "quite complex," didn't it?

A. I don't sitting here right now recall that phrase, but it wouldn't surprise me if the Court did use it.

Q. If the Court said it, would you agree with the D.C. Circuit that the application of the 180-day exclusivity period is "quite complex"?

A. Well, I thought you said a minute ago that the statute or the provisions are complex, but I would agree with both versions, both the statute and its application are complex.

Q. And just so my record's clear, both the statute is quite complex; that is, just the face of the statute is quite complex, is it not, sir?

A. Yes, it is.

Q. And then the issue of applying it to an agreement, that's quite complex, is it not, as well?

A. Yes, it is.

Q. Now, the D.C. Circuit has substantial expertise in answering questions of administrative law, does it not, sir?

A. It is generally regarded as so, yes.

Q. In fact, it's a very well-respected circuit, particularly because of its location in Washington and the number of administrative law decisions that come before that Court. Is that not the case?

A. Yes, it is.

Q. And even the D.C. Circuit, in its April 1998 opinion, did not cover the landscape and answer all of the knotty questions concerning the applicability of the 180-day exclusivity, did it?

A. No, it only addressed those in the case before

it, more or less.

Q. And one of the questions that was open and that the D.C. Circuit almost seemed to invite the FDA to address was this business about whether a meritorious second ANDA applicant should have the ability to change the operation of the 180-day exclusivity. Is that not the case?

A. FDA did -- yes, I -- the Court did seemingly invite FDA to take another crack at this.

Q. Let me direct your attention to tab 11, USX 816.

A. Got it.

Q. Got it? That's the D.C. Circuit opinion by Circuit Judge Wald in Mova vs. Shalala, is it not, sir?

A. It appears to be.

Q. And it was decided on April 14, 1998, was it not, sir?

A. It appears to.

Q. Some tens months after the June 17, 1997 agreement was entered into, correct?

A. Almost to the day.

Q. Directing your attention to page 16 of this Westlaw printout.

A. I have it.

Q. I am going to put it on the ELMO. The upper

right-hand corner, which appears to be -- excuse me -- 140 F. 3d at 1074, do you see the paragraph that begins 1074?

A. I do.

Q. Why don't you just familiarize yourself with the paragraph.

A. I've read it.

Q. Just so we're oriented, one of the things that this court decision did was cast significant doubt, if not reject fully, the successful defense regulation that the FDA had promulgated, correct?

A. Well, I believe it rejected it fully.

Q. And it did not accord the FDA Chevron deference, did the D.C. Circuit?

A. It did not.

Q. And directing your attention to the highlighted language, the Court starts out, "The problem of the meritorious second applicant is a real one, but the successful-defense requirement is too blunt an instrument to solve it." Skipping down, "We do not, of course, foreclose the FDA from attempting to address the problem of the meritorious second applicant in some narrow (sic) way, as long as that solution conforms to the statute."

Do you see that?

A. Well, actually, the Court and the opinion said "in some narrower way," but yes, with that correction, that's what the Court said.

Q. All right. So, even as of the time of this opinion, the door was cracked at least partially open for the FDA to come back with a new regulation, was it not, sir?

A. To try again, yes.

Q. And in fact, sir, subsequent to this April 1998 opinion, the FDA did put out a notice of proposed rulemaking, did it not?

A. It did.

Q. Now, did it go to a final rulemaking in that regulatory action?

A. No, that has -- that has not occurred.

Q. Okay. It doesn't mean that it might not occur in the future, but as you and I sit here talking, it has not been finalized in a final, binding rule promulgated by the FDA, correct?

A. Unless it's in the Federal Register from the last two days in which I've been in this courtroom, the answer is I don't think so.

Q. Now, sir, isn't it the case that as late as January 1999, the FDA believed they themselves needed to clarify the applicability of the 180-day exclusivity

provisions of the Hatch-Waxman Act as they related to Upsher-Smith? Isn't that the case?

A. Well, I have no idea what FDA believed.

Q. Well, why don't we take a look at tab 13, and I believe you've already answered some questions about this document.

A. This is the letter to Upsher that --

Q. Yes, sir. And it is complaint counsel's exhibit, CX 611. Do you see that?

A. Yes, I do.

Q. And in the second sentence, sir, it says, "The purpose of this letter is to clarify the 180-day exclusivity provisions under the Federal Food, Drug and Cosmetic Act with respect to your application."

Do you see that?

A. Yes, I see that sentence.

Q. So, as of the date of this letter, the FDA believed that it needed to clarify the application of the 180-day exclusivity provisions to the Upsher ANDA application. Is that not correct?

A. Well, I'm sorry, could you -- could you state the first few words of the question again, that FDA believed? Could you say that again?

Q. As of the writing of this letter on January 28th, 1999, the FDA believed that it needed to write a

letter to clarify the application of the 180-day exclusivity provisions under the Federal Food, Drug and Cosmetic Act with respect to Upsher-Smith's ANDA, did they not?

A. Well, I don't know what, if anything, FDA believed. All I know is that FDA wrote a letter.

Q. But the letter says that that's the purpose of the letter, does it not?

A. Yes, it does, and I think I should also point out to you that FDA very -- well, I apologize. You didn't ask a question, so let me withdraw the comment.

Q. All right, I'm going to probe the comment.

Sir, do you believe sitting here tonight that this sentence is false? Do you have any reason to believe this sentence is false?

A. You mean that that -- that this was the purpose of the letter?

Q. Yes, sir.

A. No, of course not.

Q. Now, you've been analyzing correspondence to and from your clients to the FDA for some 32 or 33 years. Is that not correct?

A. Make it 38.

Q. Thirty-eight?

A. Um-hum.

Q. All right. I was going to say first year of the Nixon Administration, I still remember him, but it's actually a little bit earlier than that, isn't it?

A. Well, my first involvement in FDA matters was in 1964, as a matter of fact.

Q. And I'm sure you have had many, many cases, but sir, sitting here tonight, you don't have reason to believe that in this case, with this letter, that this sentence about the purpose of the letter is a false statement by an FDA regulator, do you, sir?

A. That the purpose of the letter was to clarify the provisions with respect to Upsher's application, no, absolutely not.

Q. This letter comes some 19 months after the execution of the June 17, 1997 agreement, does it not, sir?

A. I haven't counted it, but I'm willing to assume that that's the case.

Q. Would you say it's approximately 18 or 19 months later?

A. Sure.

Q. Now, sir, despite the many years of analyzing and evaluating what comes out of the Food and Drug Administration, isn't it the case that just within the last several years, you continue to be surprised by

certain actions the FDA has taken specifically on the question of 180 days? Isn't that the case?

A. I have been surprised at various times, yes.

Q. Do you remember testifying, I think it was on direct, it might have been on cross, but the Venable Baetjer petition? Do you remember that on direct?

A. I do.

Q. And that was a petition in the spring of 1997, correct?

A. Yes.

Q. And speaking very approximately, it had something to do with the trigger for the 180 days, did it not, sir?

A. Yes, it did.

Q. Now, your report says that -- let me withdraw that and pitch it again.

The Hatch-Waxman Act was enacted in 1984, correct?

A. Yes.

Q. And the language about 180 days has been on the books since 1984, has it not?

A. It has.

Q. In the ensuing 17 or so years since the 1984 Act, the 180-day exclusivity issue has evolved quite a bit, has it not?

A. Well, there have been a series of developments relating -- relating to the issue, and the state of the law has evolved, yes.

Q. Right. And that term "evolve," that's in your report, isn't it, sir, that the 180 days has evolved over time?

A. It may be.

Q. And just listening to you on direct and even a little bit of the cross, there have been many twists and turns in the application of the 180 days. Is that not correct?

A. There have been a number of twists and turns, yes.

Q. And in some instances, sir, you've been surprised about the interpretations that the FDA has taken. Isn't that the case?

A. Yes, it is.

Q. And in fact, sir, on the very day of June 17, 1997, you were surprised that the FDA had sided, at least in part, with the Venable Baetjer petition, were you not?

A. Well, FDA didn't make any reference to the Venable -- to the Venable Baetjer petition. To the extent that FDA ruled as it did regarding the question of what court decision might trigger the 180-day

exclusivity, yes, I was surprised.

Q. In fact, you recall being dumbfounded, do you not, sir?

A. I certainly do.

Q. You had not anticipated that development for even a nanosecond. Isn't that the case, sir?

A. Not even a single nanosecond.

Q. Let me direct your attention to a new topic. You have not analyzed what Upsher-Smith actually believed in entering into the June 1997 agreement, correct?

A. Well, assuming that corporations have beliefs, no, but I haven't analyzed what anyone at Upsher might have believed either.

Q. And you haven't analyzed at a different time period, such as what Upsher might have believed in January 1998, correct?

A. With the same caveat, no, not either.

Q. And you haven't considered what Upsher-Smith actually believed as of June 1998, have you, sir?

A. Subject to the same caveats, no.

Q. Meaning that --

A. Meaning I don't know quite what a corporate belief is, but -- but if we're talking about any individual at Upsher, no, I haven't.

Q. You haven't analyzed what they were thinking about 180 days exclusivity as of June 1998, correct?

A. That's correct.

Q. Or any other date, such as January 1999, correct?

A. That's also correct.

Q. And that just wasn't your assignment, was it, sir?

A. No, it wasn't.

Q. And you have no idea sitting here what Upsher-Smith believed or did not believe on any date in this case. Is that not the case?

A. Subject to the same caveats, yes.

Q. You have no idea, correct?

A. I have -- I have no idea what anyone at Upsher may have believed or not believed at any point in time.

Q. Now, sir, you also can't answer as to the effect of Upsher-Smith's June 17, 1997 agreement in actually blocking any other generic manufacturer, can you?

A. I'm sorry, could you just restate the beginning of that question again?

Q. You actually are not in a position to testify as to whether or not any generic manufacturer has actually been blocked by the 180-day exclusivity as it

may or may not relate to Upsher-Smith. Isn't that the case?

A. I believe that I can -- I can testify as to inferences that I draw from facts that are known to me on that subject.

Q. Well, sir, you're not aware of any factual evidence of any other manufacturer actually being blocked by operation of the 180-day exclusivity. Isn't that the case, sir?

A. Well, I believe it's -- it is factual evidence that ESI Lederle has a tentative approval and that ESI Lederle has not entered the market during this period in which FDA has deemed Upsher entitled to exclusivity. So, I think I can -- I am prepared to make an inference, to draw an inference -- it's five to 7:00 since you were looking at the clock -- I believe I can draw an inference on whether ESI has been factually blocked.

Q. Before we get to inferences, let's start with The Pink Sheet. I heard over the course of your three-hour direct many references to The Pink Sheet, correct?

A. I referred to it several times.

Q. And The Pink Sheet is a way of learning facts that people in the industry might take a look at.

Isn't that the case?

A. It's a way of learning facts.

Q. Now, sir, I didn't see on any of your time lines The Pink Sheet for November 19, 2001, and you didn't refer to that in your direct testimony, did you, sir?

A. No, I didn't.

Q. Well, sir, I'm going to put on the ELMO, and I'm happy to hand you a copy of this -- in fact, let me do that.

May I approach, Your Honor?

JUDGE CHAPPELL: Yes.

BY MR. GIDLEY:

Q. Directing your attention -- have you oriented yourself, sir?

A. I have, but I haven't read the whole story yet. If you would like me to read it, you will have to give me a minute.

Q. Why don't you read the first three or four paragraphs.

A. Okay. (Document review.) I've read them.

Q. Sir, isn't it the case that readers of The Pink Sheet know that American Home Products is phasing out its oral solid dosage form generic business? Is that not the case?

A. Well, not exactly. I think what they know is that American Home Products made statements to that effect in a filing submitted to His Honor.

Q. Is K-Dur an oral generic or is it administered by some other means?

A. I believe it's considered an oral dosage form.

Q. It's ingested orally through the mouth, correct?

A. I believe so.

Q. All right, sir. And the title of the article that appeared in the Pink Sheet is "AHP Exiting Oral Generics Business; K-Dur Settlement with FTC Near."

Do you see that?

A. That's what it says.

Q. It says in the second paragraph, "In a filing submitted to the administrative law judge overseeing the FTC K-Dur case, AHP said it 'is exiting from the oral generic drug business.'"

Do you not see that?

A. That's what it says.

Q. If they have made a business decision to exit from oral generic drugs, then the 180 days can't have any effect on them. Isn't that the case?

A. Can't have any effect on them at what point in time?

Q. Well, sir, you don't contend that they're withdrawing from this business because of the 180 days, do you?

A. I have no idea why they're withdrawing from the business, but I certainly didn't suggest that as a reason.

Q. All right, sir. And in the third paragraph, the readers of The Pink Sheet learned that, "AHP has informed customers of its decision to phase out the oral solid dosage form division in July."

Do you see that?

A. Well, I see that the readers learned that that's what AHP said.

Q. And July 2001 comes before the start of the 180-day exclusivity period that you testified has been published in the Orange Book. Is that not correct?

A. Yes, that's correct.

Q. And sir, have you studied the terms of the Upsher -- strike that -- the Schering-AHP patent infringement settlement agreement?

A. No.

Q. Do you have any idea what the terms of that agreement are with respect to an entry date for AHP?

A. I have read documents that purport to describe or summarize at least some of the terms, and I do have

a general idea of what -- if my recollection is right -- as to what -- what the documents I've seen provide on that issue.

Q. Well, if you had been here for the opening arguments or opening statements, excuse me, you would have learned, sir, that the AHP/Schering-Plough agreement bars AHP from entering until 2004, would you not?

A. Would I have learned that from the opening arguments? I have absolutely no idea what I would have learned.

Q. Have you -- I'm sorry. Have you heard that date, 2004, before?

A. It sounds familiar.

Q. Now, in your direct, you didn't mention any other company being blocked during the 180 days. Isn't that the case?

A. I don't believe I mentioned any company being boxed, as you put it. I don't think I used the word "boxed," but I assume you mean excluded from the market. I don't think I referred to any particular company being excluded.

Q. And sir, you testified in your deposition, isn't it the case, that you had no idea of anyone being blocked as a matter of fact from any 180-day

exclusivity period that might apply to the Upsher ANDA. Isn't that the case?

A. As a matter of fact, I -- I had no idea, that's correct.

Q. Sir, you have not reached any conclusion as to whether Upsher-Smith would have prevailed in its patent litigation with Schering-Plough, have you, sir?

A. Oh, heavens no.

Q. And you have not reviewed the Schering patent that's at issue in this case, the '743 patent. Isn't that the case?

A. That is the case.

Q. And you haven't made any assessment as to whether or not Schering's patent is valid or invalid. Isn't that the case?

A. That also is the case.

Q. And you haven't made any determination of whether Upsher-Smith's likelihood of success was greater than or less than or equal to 50 percent, have you, sir?

A. No, I haven't.

Q. Now, this exclusivity can be waived, can it not?

A. According to FDA, it can be, yes.

Q. All right. And that's the position the FDA

takes, that it can be waived for consideration. Is that not the case?

A. That is the case.

Q. Do you know sitting here this evening whether any company has approached Upsher-Smith seeking a waiver of the 180 days?

A. I have no idea.

Q. Sir, let me direct your attention to a different topic, and that is the general effect of the pendency of the patent infringement litigation.

Sir, are you aware of any ANDA filer going to market while a patent infringement suit is pending?

A. I don't believe I am aware of one, but I would not necessarily know of it if it were so.

Q. All right, but you don't know of one sitting here tonight, correct?

A. That's correct.

Q. New topic. Your opinions that you present in your report are your own opinions, correct, sir? You formed them yourself?

A. I did.

Q. All right. And you haven't surveyed FDA lawyers in arriving at your opinion, have you, sir?

A. No, I haven't.

Q. And you are not a pharma company executive, are

you, sir?

A. No, I'm not.

Q. And you're not in a position to speculate as to what pharma company executives believed at any point in time about the 180 days overall, are you, sir?

A. Oh, I think I'm in a position to speculate as to what they might believe, any particular executive might have believed.

Q. But you're not able to do so on an informed basis; you've made no systematic survey of those executives with respect to 180 days. Is that not the case?

A. Well, are you talking about pharma executives generally or some particular pharma executives?

Q. I'm talking about pharma executives at leading pharma companies. You haven't made any systematic survey of them regarding 180 days at any point in arriving at your conclusion, right?

A. Systematic or unsystematic.

Q. No survey, right?

A. No survey.

Q. And sir, you don't represent, do you, that your report necessarily reflects the opinions, the current opinions, of FDA regulators, do you, sir?

A. Oh, I would -- I would never suggest that

anything I wrote represented the current opinions of FDA regulators, particularly on a subject where those opinions seem somewhat subject to change.

Q. Now, sir, as of June 17, 1997, you have no idea whether Upsher-Smith had any reason to believe that it was a first filer of an ANDA for K-Dur, do you, sir?

A. I don't know whether they did or not. It is possible that they did, but I'm not aware of it one way or the other.

Q. You have absolutely no idea. Isn't that the case, sir?

A. Yes.

Q. You have no idea, correct?

A. No idea, unqualified. It's a possibility, but I really don't know one way or the other, and so I have no idea.

Q. Now, sir, isn't it true that one of the purposes of the Congress in enacting the Hatch-Waxman Act was to provide an incentive for companies to challenge patents by offering a 180-day period of market exclusivity? Is that not the case?

A. I believe that to be one of Congress' purposes.

Q. And indeed, the Fourth Circuit noted that in the Granutec opinion, did it not?

A. I haven't committed the opinion to memory, but

I -- it wouldn't surprise me if it did.

Q. New topic. I'm going to be referring for the next several questions to tab 3, and I'll identify that for the record in just a minute, sir, and tab 16.

Tab 3 is a reproduction, a cull-out some of my colleagues say -- why don't you look at it in the book and I'll try to put it up on the ELMO as best I can.

A. I'm pretty much of a book person myself.

Q. All right. Have you got that page?

A. I do.

Q. All right. And we've reproduced the 180 days language from the Hatch-Waxman Act so that we could facilitate this examination. Do you see that?

A. I do.

Q. Do you recognize the language?

A. It looks familiar.

Q. All right, sir. And under the 180 Days Provision, there are two triggers in Roman caps I and II, correct?

A. Yes.

Q. All right, sir. And the second trigger states that if a court were to have decided that Upsher-Smith would win its patent infringement lawsuit against Schering-Plough, under those circumstances, there would be 180 days exclusivity. Is that not the case?

A. That's a broad paraphrase of the language, yes.

Q. Is that what would happen if Upsher-Smith had litigated in 1997 and won in a final court ruling, either that the patent was invalid or not infringed, so that it won the patent infringement lawsuit, would it not have been entitled to 180-day exclusivity?

A. Yes, it would have.

Q. Now I want to direct your attention --

JUDGE CHAPPELL: Mr. Gidley, how much more do you have?

MR. GIDLEY: I think five to ten minutes, Your Honor. It's pretty close to a wrap-up.

JUDGE CHAPPELL: We're at 7:05. Why don't we take a break. Let's recess for just ten minutes. We'll start back at 7:15.

MR. GIDLEY: Very good.

(A brief recess was taken.)

JUDGE CHAPPELL: You may proceed, Mr. Gidley.

BY MR. GIDLEY:

Q. I'd like to direct your attention to the complaint counsel binder.

A. Are we through with your binder for the moment?

Q. We are for the moment.

Let me direct your attention, sir, if I could to CX 602.

A. I have it.

Q. Now, sir, CX 602 is not copied to Upsher-Smith, is it, sir?

A. This copy of that letter is not copied to Upsher-Smith, no.

Q. And as you sit here tonight, you have no idea whether Ian Troup ever saw this in June or July of 1997. Isn't that the case?

A. Whoever Ian Troup is, no.

Q. Mr. Troup is with Upsher-Smith.

A. Oh, I'm sorry. I'm sorry, no, I -- well, I -- you're right, I have no idea.

Q. You would have no idea whether any Upsher-Smith executive actually saw CX 602. Is that not the case?

A. I have no knowledge.

Q. Similarly, CX 595, the letter dated June 18, 1997, now that was not sent to Upsher-Smith, was it, sir?

A. Not to my knowledge.

Q. And sitting here tonight, you have no idea whether Ian Troup or any other Upsher-Smith executive ever received that letter. Isn't that the case?

A. You mean -- and with reference to the prior exhibit also, specifically a copy of the letter itself? No, I have no idea.

Q. Sir, you -- let's turn to CX 605, which is The Pink Sheet of June 23, 1997.

A. Yes, I have it.

Q. All right, sir. And this is a notice in the Pink Sheet about this Novopharm preliminary injunction action, correct, sir?

A. Well, the story is about the Novopharm preliminary injunction action and the FDA actions that gave rise to it. I should say that Novopharm is the parent company of Granutec, which was the nominal -- the named plaintiff in the lawsuit.

Q. And again, sir, sitting here tonight, you have no idea whether Upsher-Smith actually received or reviewed this copy of the Pink Sheet. Isn't that the case?

A. I have no factual knowledge on that, no.

Q. You also testified about a Pink Sheet toward the end of May 1997. Do you recall that testimony on direct?

A. Yes, I do.

Q. There was a meeting of the FDLI, was there not, sir?

A. Yes, although the story actually didn't identify it as such, but I'm aware that it was an FDLI conference.

Q. And you weren't present, were you, sir?
A. No, I wasn't.
Q. And sir, you don't know whether or not Upsher-Smith was present at that meeting, do you, sir?
A. Representatives of Upsher-Smith, no, I don't.
Q. Or whether Schering was present, do you, sir?
A. Well, I don't know whether any representative of Schering was actually present at the meeting, but I do know that a Schering executive was on the program committee for that meeting. Whether he actually showed up --
Q. You don't --
A. -- for the meeting, I don't know, or whether he -- or whether he learned subsequently what occurred at this meeting, I couldn't tell you.
Q. I'm going to direct your attention back to the other binder now, sir. Let's go to tab --
A. You mean your binder?
Q. Yes, the white binder. Let's go to tab 16 where we have USX 778, a demonstrative. Do you see that?
A. Yes, I do.
Q. Now, you and Mr. Nields talked about the scenario which is a variant of Roman numeral I, that's this idea about if Upsher-Smith lost the patent

litigation. Do you recall talking about that on cross examination?

A. I do recall we talked about that. I'm not sure that's -- I'm not sure if that's Roman numeral I, but --

Q. Roman numeral I is a reference to one possible alternative outcome had there not been a settlement between Upsher-Smith and Schering-Plough, one alternative would have been a full-blown patent infringement litigation to a final decision of a court. That's what Roman numeral I refers to.

A. Okay.

Q. Okay. And you and I have just spoken about what would happen if Upsher-Smith won that lawsuit, correct, we talked about that just before the break?

A. Yes.

Q. Now, Roman numeral II, the June 17, 1997 settlement agreement, you conclude in your report and you testified here today that you believe the 180-day exclusivity applies to that settlement agreement today, correct?

A. Under current law, yes.

Q. All right. Directing your attention to Roman numeral IV -- III, excuse me, if there had been some other settlement between Upsher-Smith and

Schering-Plough, that would have also triggered the 180-day exclusivity. Is that not the case?

A. Under current law, yes.

Q. I'm going to go back to your binder, that's the black binder. Take a look at CX 1655.

A. I have it.

Q. Now, you testified on direct about this demonstrative exhibit, correct, sir?

A. Yes, I did.

Q. Now, do you consider CX 1655 to be complete and comprehensive in its treatment of the successful defense chronology?

A. Well, it picks up in October 1994, and as I testified, there was an FDA informational or guidance letter in 1988 and a couple of District Court decisions in 1989, so those would predate the start of this chart.

Q. So, 1655 omits the Inwood decision from 1989, correct?

A. It does.

Q. And it also omits the Mylan Laboratories decision from 1989, correct?

A. That's correct.

Q. And it omits the 1988 FDA letter that you testified on direct also, does it not?

A. Yes, it does.

Q. And it omits the January 1999 letter, the clarifying letter that the FDA sent to Upsher-Smith about 180 days, does it not?

A. Well, it omits all letters sent to particular ANDA applicants except -- except for the generic Zantac letters. I do not understand that the letter -- the January '99 letter to Upsher-Smith was intended as a public or broad-scale attempt to clarify or communicate anything. It was just an explanation to Upsher of where Upsher stood vis-a-vis 180-day exclusivity.

Q. All right, but it's not on this time line. This time line really is limited to the events that are culled down in the time line, correct?

A. Well, it's limited to the events that are on it, yes.

Q. All right. And let me direct your attention back to the white binder to some guidance the FDA issued in the year 2000, in March, and I don't think we've had testimony about this.

A. I think I alluded to it with Mr. Nields, but perhaps not.

Q. I direct your attention to tab 14, and what we did was we got a clean copy at tab 14 of an FDA guidance for industry on the 180-day exclusivity, and

we would be designating that USX 1036 just for identification.

Now, this document speaks as of March 2000, does it not, sir?

A. Yes, it does.

Q. And on page 1, it recites right at the beginning, the first sentence, "This guidance is being issued in response to recent litigation and is intended to provide guidance to the pharmaceutical industry."

Do you see that?

A. I'm sorry, I was just distracted by what's on the screen. Are you aware that your own demonstrative is up there still?

Q. Let's not focus on the screen. Let's just stay in USX 1036.

A. Okay, and what page were you on again?

Q. Page 1, first line.

A. Yes, that's what it says.

Q. Right. "This guidance is being issued in response to recent litigation and is intended to provide guidance to the pharmaceutical industry."

Do you see that?

A. I do.

Q. And directing your attention within the document to page 3, the second paragraph -- we can put

it on the ELMO as well. Do you see the paragraph that begins, "These recent decisions"?

A. Yes, I do.

Q. All right. And it's talking about the Torpharm decision and the Mylan Pharmaceuticals vs. Shalala decisions, is it not?

A. Yes, it does.

Q. And it says, "These recent decisions add considerable uncertainty to FDA's implementation of ANDA approval and 180-day generic drug exclusivity programs."

Do you see that?

A. It's hard to imagine that they could have added to the uncertainty, but yes, I think they did.

Q. But the state of nature for participants in this industry was that as of March 2000, there was still uncertainty about the FDA's implementation of the ANDA approval and the 180-day generic drug exclusivity. Isn't that the case?

A. Oh, no, I don't think that's the case at all.

Q. You think there was no uncertainty?

A. Well, first of all, I don't know whether the uncertainty was considerable. This is -- expresses FDA's view as of that date that there was uncertainty. I think that -- I mean, there were a number of issues

that fall under the category of FDA's implementation of the ANDA approval and 180-day exclusivity programs. I doubt, for example, that FDA meant to say that there was considerable -- still considerable uncertainty about the -- the late successful defense provision in the regulation. Whether anyone other than FDA would have believed that there was considerable uncertainty about the Mylan and Torpharm issues is another question.

Q. As of March 2000, the FDA believed that those recent decisions had added considerable uncertainty to the FDA's implementation of the ANDA approval and 180-day generic drug exclusivity programs, did it -- did they not?

A. Well, not -- not to be picky, but again, I can't speak to what Upsher believed or what FDA believed. All I know is what FDA said.

Q. But you're several years ahead of me on understanding what comes out of the FDA, and I'm just saying that this FDA document says that these court decisions have added considerable uncertainty.

A. That's what the document says.

Q. And that's what the FDA believed in March of 2000. Is that not the case?

A. I have no idea. That's what they said.

Q. Have you seen this document before tonight?

A. Oh, yes. Oh, yes.

Q. Do you have any reason to doubt that the FDA didn't believe these statements when it wrote this?

A. Well, you know, it -- again, if institutions could have beliefs. I could have some question in my mind as to whether there was all that much uncertainty at that -- at that point in time. FDA, like I guess a lot of agencies, sometimes says that there's a lot of uncertainty when they mean that they've been losing in the courts.

Q. All right. Directing your attention to the cover of this document, it says, "FDA Center for Drug Evaluation and Research, CDR."

Do you see that?

A. Yes, I do.

Q. And what is the CDR?

A. The CDR, as I explained in my direct testimony, is the unit or portion of FDA that carries out its responsibilities regarding the regulation of drugs that are not biological products.

Q. Sir, if Upsher-Smith had -- new topic.

A. Are we done with this tab?

Q. We are, sir.

I'm at tab 16 of the white binder, and it's on

the ELMO, our slide about the three different possible outcomes.

A. Oh, okay.

Q. Sir, if Upsher-Smith had not settled but instead had litigated fully with Schering and lost that patent infringement case, would Upsher-Smith have retained its 180-day exclusivity?

A. Yes, I believe it would have.

Q. And when would that 180-day exclusivity begin to run?

A. It would have begun to run on the earlier of the first to occur of the two possible trigger dates; namely, with Upsher's commercial marketing of the product under its ANDA or the decision of the court holding that the relevant patent was invalid or noninfringed.

Q. Well, the scenario I'm asking you to think about is Upsher-Smith losing the patent infringement case.

A. Yes.

Q. Have you got that scenario?

A. Oh, yes.

Q. All right. And the '743 patent, it expires September 5, 2006, does it not?

A. I -- I don't recall the exact date, but my

impression is that that's approximately right.

Q. All right. And if it expires September 5, 2006 and they've lost an infringement case, they are not going to introduce an infringing product onto the market, are they, sir? That's not very likely, is it?

A. Well, again, not to be picky, it's possible they could try to reformulate the product and take the position that this particular formulation didn't infringe and try to introduce that one.

Q. Let's take --

A. Or to do so through an amendment of the ANDA, which is exactly what Genpharm did.

Q. Let's take on your scenario. Do you tonight sitting here have any idea of a noninfringing formulation that would allow Upsher-Smith to get around the '743 Schering patent, sitting here tonight?

A. Do I -- I'm not sure what you mean by do I have any idea of a noninfringing formulation. I can -- I can form the idea and hold it in my mind. Yes, I think such a thing is possible.

Q. Well, that's great philosophically, but I mean in the real world, are you aware of any chemical compound that would perform like K-Dur 20 and not infringe the '743 patent sitting here tonight?

A. Well, you're getting out of not only any

expertise I might have but any -- any experience, but my understanding of the K-Dur patent is that it's a formulation patent, and the patent is not on the compound itself, potassium chloride, and so I don't find it as startling as you seem to that there could be a different formulation that would not infringe the patent.

Whether -- whether such a thing has been developed by anybody to this point, obviously I have no idea. Whether one ever will be developed by anyone, I even more clearly have no idea.

Q. Okay, I want you to exclude Cartesian doubt. I just want to stay in the world of -- at the realm of the plausible, and sitting here tonight, you are not aware of a chemical compound that my client could use to get around the '743 patent. Is that not the case?

A. Well, my doubts were not -- I was not trying to express Cartesian doubt. I was trying to express what I in my own nonpatent lawyer and nonchemist way certainly considered to be plausible, but having got the -- your statement out of the way, am I actually aware of such a formulation existing today, no, I'm not.

Q. And even if reformulated -- let's just say hypothetically there's just some reformulation, so

that's a new hypothetical -- even if there was a new formulation, there might be a whole new round of infringement litigation, might there not, sir?

A. There might or there might not.

Q. And if there's patent infringement litigation and if Upsher-Smith's a Paragraph IV filer, then there might be a 30-month stay if the suit occurred in that first 45 days within the notice period. Isn't that the case, sir?

A. If all those contingencies came to pass, yes, or there might not be -- or there might not be a suit. We might have a replay of the -- I believe the Mova fact pattern in which the second ANDA filer came up with a new formulation and wasn't sued.

Q. All right. Your report was written about 16 days before the magic date of September 1, 2001. Is that not the case?

A. Well, before the -- it was written 16 -- about 16 days before September 1. Whether that was a magic date, I can't speak.

Q. And you had the benefit of four more years of court decisions and FDA promulgations and statements concerning 180 days than my client did. Isn't that the case?

A. Than your client did when?

Q. In June of 1997.

A. Yes, of course.

Q. And sir, in your report, you don't predict Schering-Plough coming out with its own generic, do you, on or about September 1, 1997?

A. No, I didn't discuss the possibility of that at all.

Q. And sir, you didn't predict a company called Qualitest to be selling a potassium chloride 20 mEq product starting during the 180-day period from September 1, 2001 to February 28, 2002, did you?

A. I've never heard of Qualitest, and if you're suggesting that that's a separate entity from the Schering-Plough corporate family, I have no idea if it is or not.

Q. Never heard of Qualitest?

A. Never heard of it.

MR. GIDLEY: No further questions.

JUDGE CHAPPELL: Redirect?

MR. NARROW: Your Honor, I realize it's late. If we could take just a couple of minutes with -- for me to speak with Mr. Hoffman before redirect, I think my redirect will be very brief.

JUDGE CHAPPELL: To speak to the witness?

MR. NARROW: Before redirect, I believe once

cross is closed.

JUDGE CHAPPELL: Any objection?

MR. GIDLEY: Your Honor, I -- you know, other than a physiological break for a minute or two, I would object. I think that this testimony is relatively straightforward, and it is what it is at this point in the evening.

JUDGE CHAPPELL: So, you don't object to a two or three-minute break?

MR. GIDLEY: No, Your Honor.

JUDGE CHAPPELL: Go ahead.

MR. NARROW: Thank you.

JUDGE CHAPPELL: What about Schering?

MS. SHORES: No objection, Your Honor.

JUDGE CHAPPELL: I'm sorry, I didn't see you behind that monitor. Go ahead.

(Pause in the proceedings.)

JUDGE CHAPPELL: Okay, go ahead, Mr. Curran.

MR. CURRAN: Thank you, Your Honor, a couple of quick housekeeping matters.

Your Honor may recall that during my examination of Dr. Levy, there were certain documents that I was preparing to move into evidence but had not had the documents marked for that purpose. The documents have now been marked and a couple hours ago

were provided to complaint counsel and to counsel for Schering, and I'd like to consummate the motions for the admission of those documents at this time, if I may.

JUDGE CHAPPELL: Okay.

MR. CURRAN: The first document was the annual report --

JUDGE CHAPPELL: All I need are the exhibit numbers, Mr. Curran.

MR. CURRAN: Very good. Your Honor, USX 1025, USX 1026, USX 1027, USX 1028, USX 1029, those are all for -- as substantive evidence, and then as a demonstrative only, USX 1030.

JUDGE CHAPPELL: Hold on a second. Hold on. Any objection to USX 1025, 1026, 1027, 1028 or 1029?

MS. BOKAT: No, Your Honor.

MS. SHORES: None for Schering, Your Honor.

JUDGE CHAPPELL: Okay, USX 1025, 1026, 1027, 1028 and 1029 are admitted.

(USX Exhibit Numbers 1025 through 1029 were admitted into evidence.)

MR. CURRAN: Thank you, Your Honor.

Frankly, I'm not sure what the process is we're following with regard to demonstratives, but there have been a couple of motions made today for the admission

of demonstratives, and in accordance with that practice, I'd like to move for the admission of USX 1030 as a demonstrative, also provided to complaint counsel and counsel for Schering earlier.

JUDGE CHAPPELL: Any objection?

MS. BOKAT: No, Your Honor.

MS. SHORES: No, Your Honor.

MR. CURRAN: Finally, Your Honor, I understand --

JUDGE CHAPPELL: USX 1030 is admitted as a demonstrative exhibit.

(USX Exhibit Number 1030 was admitted into evidence.)

MR. CURRAN: Thank you, Your Honor.

Finally, I understand that the motion filed yesterday by complaint counsel regarding certain attorney-client issues --

JUDGE CHAPPELL: Right, that's the second front that's going on while we're in here, and I haven't read these yet, because I didn't get the response yet, but -- I'm sure I'll be reading them tonight, but go ahead. I just wanted to let you know that I haven't read the motion.

MR. CURRAN: Very good. I have not either, Your Honor, but I understand that it addresses

Upsher-Smith as well. We will plan on responding to that after having read the motion. We do not have any witnesses that we are going to be calling in the next few days that are the targets of that motion, but I wanted to let Your Honor know those circumstances for when you read the motion papers tonight or tomorrow.

Given the circumstances, we do not object to Your Honor considering the motion as it affects Schering without awaiting any opposition from Upsher-Smith.

JUDGE CHAPPELL: When do you anticipate having your response filed?

MR. CURRAN: It would be difficult tomorrow, Your Honor, but we could file it on Friday.

JUDGE CHAPPELL: What's this? This is Wednesday?

MR. CURRAN: I think so.

JUDGE CHAPPELL: I think we've decided that tomorrow will be Schering-Plough's witnesses. The only thing I require is I, of course, need your response before these witnesses are called.

MR. CURRAN: Very good. It will not be a problem.

JUDGE CHAPPELL: Friday should be acceptable.

MR. CURRAN: We will have it filed well before

any of our witnesses will be called.

JUDGE CHAPPELL: Okay, and you had raised the issue of a demonstrative exhibit. To me, a demonstrative exhibit is the same as an exhibit for identification. It's not substantive evidence. It's something that's assisting a witness in the testimony. Does that help?

MR. CURRAN: That's consistent with my understanding of how it ought to be, Your Honor.

JUDGE CHAPPELL: Any questions on that from the Government?

MS. BOKAT: No, Your Honor.

JUDGE CHAPPELL: Schering?

MS. SHORES: No, Your Honor.

JUDGE CHAPPELL: Is that all, Mr. Curran?

MR. CURRAN: Yes. Thanks for your patience.

JUDGE CHAPPELL: Redirect, Mr. Narrow?

MR. NARROW: Yes, thank you, Your Honor.

JUDGE CHAPPELL: You may proceed.

REDIRECT EXAMINATION

BY MR. NARROW:

Q. Mr. Hoffman, I believe that Mr. Gidley, in referring to tab 16 of his binder of exhibits, asked you the question, unless I misheard, it was with regard to number III on that document if there had been

another settlement, and I thought I heard you answer that there -- that such a settlement would have triggered any 180-day exclusivity held by Upsher. Was that what you intended to say?

A. No. What I thought I heard, and maybe I missed the key word, no pun intended, was that some other form of settlement would still have left Upsher entitled to exclusivity. I didn't mean to refer to either the commercial marketing or the court decision trigger, and if I -- if I missed that word and misspoke, I apologize to Mr. Gidley.

Q. Okay, thank you.

Now, Mr. Gidley also was at one point I think referred to the January 28th, 1999 letter from FDA to Upsher-Smith. I believe that was CX 611 in which they clarified the status of Upsher-Smith's exclusivity, 180-day exclusivity. That letter, again, CX 611, in the first sentence refers back to the November letter, which was I believe CX 59. Is that correct?

A. Yes, it is.

Q. Okay. And did the letter CX 59, which granted final approval to Upsher, did that have any information concerning Upsher's exclusivity in it?

A. Yes, the January 28th, 1999 letter --

Q. No, CX 59.

A. Oh, I'm sorry. No, it didn't. It simply didn't mention the point.

Q. Okay. And CX 611, which was the January letter to Upsher, do you have any understanding in your mind as to what the term "clarifying" is referring to there concerning exclusivity?

A. Well, as I -- as I read the letter, it was simply to clarify for Upsher that as -- that it, in fact, was entitled to 180-day exclusivity. It -- I didn't read this as some broadly applicable clarification of general issues under the law. It was just spelling out what perhaps could have been or even should have been included in the November letter.

Q. Okay. Now, earlier, when Mr. Nields was cross examining you, he asked you a question as to why -- he asked you whether, in fact, it was the case that in the report you said nothing concerning what FDA had said about settlements, either in the Teva letter or in the Fourth Circuit brief. Do you recall that question?

A. Yes, I do.

Q. And you offered to explain why you had not included those in your report, and Mr. Nields did not permit you to continue and answer that question. So, I want to ask you why did you not include that information in your report concerning settlements?

A. I didn't specifically mention it because the important point or the -- let us say the underlying premise of FDA's position in the Teva letter and then again in the Fourth Circuit was subsumed, the -- well, there was an underlying premise; namely, that FDA could interpret the statute in this general way to deny exclusivity to a first filer. I addressed that general point and the fact that FDA's underlying rationale was rejected by the District Court, and there was no need to spell out the logical implication of that for the specific settlement point.

Q. Okay. Now, you testified earlier in your direct testimony that Upsher-Smith currently, unequivocally has 180-day exclusivity. Is that correct?

A. Well, I said unquestionably, yes.

Q. Excuse me, I apologize for misquoting you. Unquestionably has exclusivity. Is that correct?

A. Yes, I did.

Q. Upsher settled its patent infringement litigation, didn't it?

A. That's my understanding.

MR. NARROW: No further questions, Your Honor.

JUDGE CHAPPELL: Recross?

MS. SHORES: None for Schering, Your Honor.

MR. GIDLEY: Very brief, Your Honor, with Your Honor's indulgence and the court reporters' indulgence.

JUDGE CHAPPELL: We're here to serve, Mr. Gidley.

MR. GIDLEY: Excuse me?

JUDGE CHAPPELL: We're here to serve. Go ahead.

MR. GIDLEY: Thank you, Your Honor.

RECROSS EXAMINATION

BY MR. GIDLEY:

Q. Can you take a look, sir, at the 180 days provision?

A. I'm looking.

Q. You may have memorized it, but it's now on the ELMO. Do you see that?

A. I'm looking and I see it.

Q. All right. And I also want you to think about, and we can flip to it in the binder, tab 16 of the white binder, the three possibilities. Are you there?

A. I'm there.

Q. Okay. You've concluded that the middle outcome, the June 17, 1997 settlement agreement, has today, under your current understanding of the law, triggered a 180-day exclusivity period, correct, sir?

A. Well, you're using the word "trigger," and I

had -- the first time -- if you used it before, I understood you to mean left Upsher entitled. If you're using it in that sense, I would agree with you. If you are using it in the -- in the sense of triggering -- of triggering the court -- of serving as the court decision trigger or the commercial marketing trigger, no, I would not agree with that.

Q. Fine, let's keep it very precise.

The June 1997 agreement that was actually entered into permits Upsher-Smith to begin marketing on September 1, 2001. Is that not your understanding of the agreement that was actually entered into?

A. That's my understanding.

Q. And as of that first commercial marketing of Klor Con M20, their substitute product for K-Dur, at the beginning of that, the 180 days kicked in under today's understanding of the law. Is that not your opinion?

A. That is my opinion.

Q. All right, sir. Now, directing your attention to slide 16, if instead of that settlement some other settlement had occurred such that -- let's just take a hypothetical date -- such that the parties agreed that Upsher could begin marketing on September 1, 2002, and let's also assume that we're going under current law

and there's no change in the law, but it's September 1, 2002 instead of September 1, 2001, if Upsher-Smith began commercial marketing on September 1, 2002 under that hypothetical, the 180 days would be triggered under current law, correct?

A. Yes, that's correct.

Q. So, sir, sitting here today, using today's law, any settlement agreement entered into between Upsher-Smith and Schering-Plough back in June of 1997 that would provide for commercial marketing as of a date certain, as of that date, would trigger the 180 days when that commercial marketing begins under that trigger, correct?

A. I think that's a convoluted way to put it. I would not say that the settlement triggers anything. It's the commercial marketing that triggers the 180 days.

Q. Fine. Any settlement agreement that has -- say that gets entered into in June of '97 and provides for an entry date, we're using today's law, any settlement agreement that provides for an entry date and entry does occur and commercial sales begin, at the time of those commercial sales, with no other facts being changed, would trigger the 180 days. Is that not correct?

A. Again, it's a convoluted sentence, but if I heard it right, you're asking me whether the settlement agreement triggered the exclusivity, and I don't think that's so.

Q. As you sit here tonight, is there any settlement agreement my client could have entered into that has an entry date in it that would not have triggered the 180 days at the time my client begins commercial marketing of the product?

A. Well, at the risk of repeating myself, I think your question repeats itself. I don't think any settlement agreement, as a settlement agreement, triggers exclusivity. The commercial marketing does, whether it's pursuant to a settlement agreement or because of a belief that -- that the applicant will take his chances with patent litigation, assuming that the 30-month stay has run. The -- it's the commercial marketing that triggers the exclusivity. It has nothing to do with the settlement.

Q. But sir, any settlement agreement that provides for an entry date and on or about that entry date commercial marketing begins, the trigger of the 180 days kicks in with no other facts being changed. Isn't that correct?

A. The trigger kicks in when the commercial

marketing begins. It has nothing to do with the settlement.

MR. GIDLEY: No further questions.

JUDGE CHAPPELL: Anything further?

MR. NARROW: No, Your Honor, thank you.

MS. SHORES: Nothing for Schering, Your Honor.

JUDGE CHAPPELL: Thank you, Mr. Hoffman. You're excused.

THE WITNESS: Thank you, Your Honor.

(Discussion off the record.)

JUDGE CHAPPELL: Due to the lateness of the hour, we are going to adjourn for the night. We are going to reconvene tomorrow at noon. Thank you.

(Whereupon, at 7:55 p.m., the hearing was adjourned.)

C E R T I F I C A T I O N O F R E P O R T E R

DOCKET/FILE NUMBER: 9297

CASE TITLE: SCHERING-PLOUGH/UPSHER-SMITH

DATE: FEBRUARY 6, 2002

I HEREBY CERTIFY that the transcript contained herein is a full and accurate transcript of the notes taken by me at the hearing on the above cause before the FEDERAL TRADE COMMISSION to the best of my knowledge and belief.

DATED: 2/7/02

SUSANNE BERGLING, RMR

C E R T I F I C A T I O N O F P R O O F R E A D E R

I HEREBY CERTIFY that I proofread the transcript for accuracy in spelling, hyphenation, punctuation and format.

DIANE QUADE